Board of Examiners in Optometry
PO Box 513
Wall, SD 57790
sdoptboard@goldenwest.net
Telephone: (605) 279-2244
Website: http://optometry.sd.gov

AGENDA

Monday, August 28, 2023
In-Person Meeting
AmericInn- Conference Room
312 Island Drive, Fort Pierre, SD 57532
8:00 a.m. (CST)

1. Approval of Agenda

2. Board Member Request for Conflict Waiver

3. Public Comment

4. Approve minutes from the in-person meeting on April 3, 2023, and virtual meetings on June 28, 2023, and August 8, 2023.

5. Treasurer's Report
   a. Financial Reports
   b. Database/Renewal Software Update

6. Board Review and Approve CE Courses
   a. Non-COPE CE Approval

7. Old Business
   a. National and State Issues Monitored
   b. Statute & Administrative Rule Review

8. New Business
   a. Licensing (5)
   b. Petition for Declaratory Ruling regarding Intense Pulsed Light (IPL)

9. Time and place of next meeting

10. Adjournment

Individuals needing assistance, pursuant to the Americans with Disabilities Act, should contact the in Board of Examiners in Optometry (605-279-2244) or sdoptboard@goldenwest.net at least 24 hours advance of the meeting to make any necessary arrangements.

The public may listen to and participate in the meeting by calling 1-253-215-8782 (Meeting ID: 673 963 1412). Zoom link: https://us02web.zoom.us/j/6739631412

REQUEST FOR WAIVER

SDCL 5-18A-17 to 5-18A-17.6

THIS IS A PUBLIC DOCUMENT

Date:_____
Employee Name:_____
Employee Signature: _____
Agency:_____
Position No:_____
Title:_____

Brief explanation of your potential conflict of interest:

Brief explanation of your role in the award, administration or supervision of a contract with an outside party or your current or anticipated business transaction with a state agency (other than a contract of employment):

Brief explanation of why you believe a waiver should be granted:

FOR AGENCY/BHR USE ONLY:
Date received by official acting on request:
Signature of Official acting on request:_____
Date of interview:
Date acted upon:
Waiver granted? Y/N
If waiver is conditional, so note here (Y/N), list conditions
on separate sheet and attach to this document.
Appeal requested? Y/N
Appeal received in Governor's Office:
Date appeal acted upon:
Waiver granted on appeal? Y/N
Received by BHR:

South Dakota Board of Examiners in Optometry
Meeting Minutes
April 3, 2023
8:00 AM (CST)
Zoom Virtual Meeting

DRAFT MINUTES HAVE NOT BEEN APPROVED BY THE BOARD

Board Members		Board Staff Present
Ashley Crouch, OD	Present	Deni Martin, Executive Secretary
Jamie Farmen, Consumer Member	Present	Megan Borchert, Board General Counsel
Brian Gill, OD	Present	**Guests**
Angela Hase, OD, President	Present	Deb Mortenson, South Dakota Optometric Society
Scott Schirber, OD	Present	Benjamin Uhl
		Eric Erickson

Attendance: President Hase called the meeting to order at 8:00 AM on April 3, 2023.

1. Approval of Agenda:

Board Action: A Crouch moved to approve the agenda, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

2. Conflict of Interest: All board members reported no conflict with agenda items.

3. Public Comment: No public comment

4. Approval Minutes:

Board Action: J Farmen moved to approve the minutes from the regular meeting on August 22, 2022, and the Zoom/telephonic meeting on April 25, 2022, seconded by S Schirber. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

5. Financial Reports:

Board Action: D Martin presented the treasurer's report found on pages 8-10 of the agenda packet. B Gill moved to accept treasurer's report, seconded by A Crouch. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

D Martin reported on the progress of the database upgrade. It's currently in testing and should be ready to use for the next license renewal period starting July 1, 2023.

6. Board Review and Approve Non-COPE CE Courses:

Board Action: Since this meeting was previously scheduled to take place in-person, but the weather forecast caused us to move it to a Zoom meeting, S Schirber moved to authorize President Hase to review and approve any Non-COPE CE courses submitted from the last meeting through April 3, 2023, seconded by A Crouch. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

7. Old Business

A. National and State Issues Monitored: Deb Mortenson, Executive Director for the South Dakota Optometric Society, provided updates regarding some efforts by states to limit optometrists using the description of "doctor", limits to Medicare/Medicaid reimbursements, and a new DEA continuing education requirements for opioid training. The SDOS is exploring options for providing CE to help fulfill these requirements. No other new information or action taken, but issues will continue to be monitored.

8. New Business:

A. Licensing:

Board Action: Pursuant to SDCL 1-25-2, S Scirber moved to enter into executive session to consult with legal counsel regarding a licensing matter, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board entered into executive session at 8:22am and moved out at 9:05am.

At this time, D Martin indicated that Benjamin Uhl had entered into the Zoom meeting after the public comment timeframe of the approved agenda. President Hase offered him the opportunity to speak at this time. He indicated that he's here to speak on the current CE requirements regarding automatic COPE approval and anything non-COPE being approved by the board. He is currently licensed in South Dakota, Iowa, Nebraska and inactive license in Texas. He's the Chair of the Iowa Board of Optometry and on the board of the Iowa Optometric Association; however, he is representing himself and he is not here on behalf of either of those boards. Iowa eliminated participation in COPE because he feels it limits options for CE and creates a burden for presenters. He is asking this board to reconsider its position regarding non-COPE continuing educatoin and allow more automatically approved non-COPE CE from state associations, the AOA, American Academy of Optometry, schools of optometry and ophthalmologists. He was thanked for his comments.

B. Scope of Practice Decision Making Framework and Petition: President Hase indicated that, now that the procedure code list has been removed from state administrative rule, this board needs to discuss a plan regarding scope of practice inquiries. Megan Borchert

presented a scope of practice decision making-framework document on page 20 of the agenda packet, this similar to what the Board of Nursing uses. This document will be provided to individuals to consult with their own legal counsel. If a further declaratory ruling is requested from this board, the information regarding how to submit a scope of practice petition, found on page 21 of agenda packet, shall also be provided to licensees and the public.

Board Action: B Gill moved to approve the decision making-framework document, seconded by S Schirber. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: A Crouch moved to approve the declaratory ruling process document, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: B Gill moved to approve that both documents be posted to the public website, seconded by S Schirber. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

C. Contracts:

Board Action: A Crouch moved to approve the FY24 contract for the South Dakota Optometric Society using the same terms as FY23, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: S Schirber moved to approve the FY24 contract for Codewise, with a not to exceed amount of $10,000, seconded by B Gill. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: S Schirber moved to approve the FY24 contract for Scott Kennedy using the same terms as FY23, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: A Crouch moved to approve the FY24 contract for Lisa Kollis-Young using the same terms as FY23, seconded by B Gill. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

Board Action: At 9:25am, J Farmen moved to enter into executive session pursuant to SDCL 1-25-2 to prepare for contract negotiations, seconded by A Crouch. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

* The board moved out of executive session at 9:46am.

Board Action: S Schirber moved to approve the contract for Deni Martin for FY24 with a 7% increase in salary, a 10% increase in office rent, a 15% one-time bonus from current salary to cover additional duties applying to the database design and upgrade. Other terms to remain the same as FY23, with a not to exceed amount of $47,611.33, seconded by J Farmen. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

9.Time and Place of Next Meetings:

Monday, August 28, 2023- In-Person Meeting
AmericInn- Conference Room
312 Island Drive, Fort Pierre, SD 57532
8:00am (CST)

10. Adjournment:

Board Action: J Farmen moved to adjourn meeting at 9:52am, seconded by B Gill. Vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

South Dakota Board of Examiners in Optometry

Virtual Meeting Minutes

June 28, 2023
6:00PM (CST)

DRAFT MINUTES HAVE NOT BEEN APPROVED BY THE BOARD

Board Members		Board Staff Present
Angela Hase, OD, President	Present	Deni Martin, Executive Secretary
Scott Schirber, OD. Vice President	Present	Megan Borchert, Legal Counsel
Ashley Crouch, OD	Present	
Brian Gill, OD	Present	**Public Attendance**
Jamie Farmen, Consumer Member	Present	Deb Mortenson, South Dakota Optometric Society Jennifer Stalley, South Dakota Optometry Society

* A call-in number and physical location were noticed as available for public access to listen to and participate in the meeting.

1. Attendance: President Hase called the meeting to order at 6:00 PM on June 28, 2023.

2. Approval of Agenda

Board Action: B Gill moved to approve the agenda, seconded by J Farmen. Roll call vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

3. Conflict of Interest: No conflict of interest reported.

4. New Business: Administrative Rule Review

The board reviewed current administrative rule changes to align with the American Optometric Association Standards of Professional Conduct and related publications. Board members provided comments on current administrative rules with the recommendation that legal counsel draft a new proposed administrative rule document. They requested that it be submitted to the South Dakota Optometric Society for feedback to be considered during the next meeting. They requested another Zoom meeting to further discuss any potential administrative rule changes. No formal action taken.

5. Public Comment: Deb Mortenson reported that the South Dakota Optometric Society appreciates the opportunity to provide feedback on the proposed rules prior to the next meeting.

6.Time and Place of Next Meeting:

Next Meeting: Zoom/Virtual: Tuesday, July 11, 2023, at 6:00pm CST.

7. Adjournment:

Board Action: At 6:47pm, A Courch moved to adjourn meeting, seconded by J Farmen. Roll call vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	YES
Gill	YES	5 YES, MOTION CARRIED	

South Dakota Board of Examiners in Optometry

Virtual Meeting Minutes

August 8, 2023
6:00PM (CST)

DRAFT MINUTES HAVE NOT BEEN APPROVED BY THE BOARD

Board Members		Board Staff Present
Angela Hase, OD, President	Present	Deni Martin, Executive Secretary
Scott Schirber, OD. Vice President	Absent	Megan Borchert, Legal Counsel
Ashley Crouch, OD	Present	
Brian Gill, OD	Present	**Public Attendance**
Jamie Farmen, Consumer Member	Present	Deb Mortenson, South Dakota Optometric Society
		Jennifer Stalley, South Dakota Optometry Society

* A call-in number and physical location were noticed as available for public access to listen to and participate in the meeting.

1. Attendance: President Hase called the meeting to order at 6:00 PM on August 8, 2023.

2. Approval of Agenda

Board Action: A Crouch moved to approve the agenda, seconded by J Farmen. Roll call vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	ABSENT
Gill	YES	4 YES, MOTION CARRIED	

3. Conflict of Interest: No conflict of interest reported.

4. New Business: Statute Review

The board reviewed SDCL 36-7-15 with section 2 amended to provide the Board explicit authority for inspections and to develop rules to regulate the provision of telehealth services. B Gill moved to begin the legislative process to amend 36-7-15, seconded by A Crouch. Roll call vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	ABSENT
Gill	YES	4 YES, MOTION CARRIED	

Discussion was had that the Board intended to share the draft with stakeholders for additional input to get it submitted to the SD Department of Health ahead of the August 15 deadline.

5. Public Comment: Jennifer Stalley commented on behalf of SDOS. She thanked Megan Borchert talking through issues with them in earlier drafts. Since the SDOS board has not met regarding this specific statute, she was not able to give an official stance of their board, but she appreciates the work Megan put into moving this draft to this stage. They would like to wait to see what the SD Department of Health (DOH) says and what this board decides to do. Deb Mortenson concurred with Jennifer's statements via the Zoom chat as her audio was not working to be able to verbalize comment.

6. Time and Place of Next Meeting:

IN-PERSON MEETING:
Date: Monday, August 28, 2023
Time: 8:00AM (CST)
Location: AmericInn- Conference Room, 312 Island Drive, Fort Pierre, SD 57532

7. Adjournment:

Board Action: At 6:10pm, J Farmen moved to adjourn meeting, seconded by A Crouch. Roll call vote:

Crouch	YES	Hase	YES
Farmen	YES	Schirber	ABSENT
Gill	YES	4 YES, MOTION CARRIED	

Subobject	Description	FY15 Actual	FY16 Actual	FY17 Actual	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Actual	FY22 Actual	FY23 Actual	FY24 8/15/2023
	Salaries										
5101030	Board & Comm Members	660	780	900	660	600	1,020	180	1,800	1,080	300
5102010	OASI-Employer's	51	61	69	50	46	81	14	138	85	23
5203010	Auto-State										
	Board Member Travel	855	1,229	1,002	1,467	1,482	2,131	-	1,114	1,058	-
	*Includes: Auto, Meals, Lodging										
5204020	Dues & Memberships	750	750	750	750	750	850	850	850	850	
5204060	Ed & Training	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000	
5204050	Computer Consultant (database)	406	1,595	175	350	315	128	765	128	21,675	-
5204100	Medical Consultant (investigator)	-	360	2,140	-	753	-	248	-	158	
5204080	Legal Consultant	16,949	12,623	30,665	26,376	15,388	21,202	7,150	7,196	7,647	-
5204090	Management Consultant	28,588	31,703	33,924	34,541	35,214	35,251	34,366	37,051	42,657	10,098
5204180	Computer Services- State			213	158	62	76	84	90	261	75
5204200	Central Services: Misc DOH	802	828	1,125	1,115	1,195	1,262	1,069	1,062	1,411	350
5204204	Central Services: Records	233	192	192	199	245	286	274	246	246	67
5204207	Central Services: HR	208	242	293	230	205	360	44	524	519	
5204960	Other Contractual					75					
5205310	Printing-State		1048			385	626	482		620	
5204590	Ins Premiums & Surety Bds	740	380	335	815	900	880	245	825	995	
5205350	Postage		36			9		13		30	
5207905	Computer	1868									
5207451	Office Furniture and Fixtures										
5207491	Telephone Equipment							25			
5207901	Computer Hardware							157			
52053901	Food Stuffs						24				
	TOTAL EXPENSES	**56,110.00**	**55,827.00**	**75,783.00**	**70,711.00**	**61,624.00**	**68,177.00**	**49,966.00**	**55,024.00**	**83,292.00**	**10,913.00**
	TOTAL REVENUE	**54,491.16**	**71,403.85**	**72,734.74**	**73,801.78**	**75,524.55**	**75,454.24**	**76,015.09**	**74,391.35**	**74,471.27**	**7,032.40**
	REVENUE - EXPENSES	-1,618.84	15,576.85	-3,048.26	3,090.78	13,900.55	7,277.24	26,049.09	19,367.35	-8,820.73	-3,880.60

	CASH CENTER BALANCE	**36,406.28**	**51,986.12**	**48,935.18**	**52,025.36**	**65,925.77**	**73,202.49**	**94,237.52**	**113,607.19**	**104,787.20**	**100,906.76**

2024 Bill Draft: DOH-##

Most recent version as of**: 3:55 PM 8/1/2023**

FOR AN ACT ENTITLED, **An Act to revise certain provisions related to the licensure of Optometrists pursuant to SDCL 36-7.**

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. That § 36-7-15 be AMENDED:

36-7-15. The board may:

(1) Promote the safe and qualified practice of optometry;

(2) Promulgate rules pursuant to chapter 1-26 to govern standards for the safe and qualified practice of optometry, to provide office inspections, to govern the provision of telehealth services, to adopt a code of ethics or professional conduct, and to establish criteria for advertising by optometrists;

(3) Prepare an annual budget;

(4) Expend funds for administrative, legal, consultative, and other necessary services from fees received by the board;

(5) Examine, license, endorse, and renew the licenses of qualified applicants;

(6) Define what constitutes a recognized optometric school;

(7) Establish the minimum amount and type of continuing education to be required of each optometrist seeking renewal of a license; and

(8) Administer oaths and take testimony pursuant to §§ 1-26-19.1 and 1-26-19.2.

FROM THE DESK OF
ERIC ERICKSON

CUTLER LAW FIRM, LLP
140 N Phillips Avenue
4th Floor
Sioux Falls, SD 57104
(605) 335-4950 main
(605) 271-4938 direct
(605) 335-4961 fax

August 10, 2023

VIA MAIL:

South Dakota Board of Examiners in Optometry
Deni Martin, Executive Secretary
PO Box 513
Wall, SD 57790

VIA ELECTRONIC MAIL:

Deni Martin: sdoptboard@goldenwest.net
Megan Borchert: Megan.Borchert@state.sd.us
Deb Mortenson: deb.mortenson@pie.midco.net
Justin Sweitzer: justin.schweitzer@vancethompsonvision.com

Re: South Dakota Optometric Society-Petition for Declaratory Judgement

To whom it may concern:

Please be advised that our firm represents the South Dakota Optometric Society ("SDOS"). Enclosed please find petitions from the SDOS requesting a declaratory ruling, pursuant to South Dakota Codified Law 36-1C-14 through 36-1C-16 and the South Dakota Board of Examiners in Optometry Scope of Practice Declaratory Ruling Process, confirming the use of Intense Pulsed Light, as more-fully described within the petition, is within the scope of practice for optometry set forth in South Dakota Codified Law 36-7-1.

Should you have any questions regarding this petition or the request for delay, please do not hesitate to contact me at (605) 271-4938, at the address above, or via email at erice@cutlerlawfirm.com.

Sincerely,

CUTLER LAW FIRM, LLP

Eric E. Erickson
For the Firm

EEE/apr

PETITION FOR DECLARATORY JUDGMENT

Pursuant to the provisions of SDCL 1-26-15, I, Eric E. Erickson, of Cutler Law Firm, LLP, located at 140 N. Phillips Ave., Sioux Falls SD 57104, am legal counsel for the South Dakota Optometric Society, and do hereby petition the South Dakota Board of Examiners in Optometry for its declaratory ruling in regard to the following:

(1) THE STATUTES OR RULES OR ORDER IN QUESTION ARE/IS:

The South Dakota Optometric Society ("***SDOS***") respectfully requests the South Dakota Board of Examiners in Optometry issue a declaratory ruling confirming the use of Intense Pulsed Light ("***IPL***"), as more-fully described in Sections 2 and 3, is within the defined scope of practice for optometry set forth in SDCL § 36-7-1.

(2) THE FACTS AND CIRCUMSTANCES THAT GIVE RISE TO THE ISSUE TO BE ANSWERED BY THE PROFESSIONAL OR OCCUPATIONAL BOARD OR COMMISSION'S DECLARATORY RULING:

Overview: IPL is a non-laser light-based medical device with a protocol useable in the treatment of dry eye disease used by optometrists in over forty-five states.[1] IPL uses bursts of light directed at eyelids and upper cheek areas to heat the eyelid glands that are blocked with stagnant secretions; the generation of heat and subsequent destruction of targets occurs "through a process called selective photothermolysis."[2] A doctor of optometry ("***OD***") may then be able to manually express the stagnant material from the eyelids after IPL treatment.[3] IPL is applied only to skin on the malar region of the face, from tragus to tragus, including the nose.[4] Eyes would be fully covered by protective eyewear.[5]

IPL treatment provides relief for patients who have exhausted or failed to tolerate other treatment options such as drops or compresses.[6] In 2016, a study stated, "Intense pulsed light (IPL) therapy is a safe and efficient treatment in relieving symptoms and signs of [meibomian gland dysfunction] MGD eyes."[7] More recently, Deepon Kar, OD, stated in her January 19, 2023 article in Ocular Surface titled The Role of Intense Pulsated Light in Dry Eye Management:

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[1] As more fully described below in Footnote 14.

[2] D. Piccolo, et al., *Unconventional Use of Intense Pulsed Light*, BIOMED RSCH. INT'L. 2014: 618206.

[3] Guanghao Qin, et al., *Efficacy of Intense Pulsed Light Therapy on Sign and Symptoms of Dry Eye Disease: A Meta-analysis and Systematic Review*, Indian J. Ophthalmology, 71(4): 1316-25 (2023).

[4] *Id.*

[5] *Id.*

[6] Russel Lazarus, *Dry Eyes: What is Intense Pulsed Light Therapy?*, OPTOMETRISTS NETWORK (Dec. 13, 2020), https://www.optometrists.org/general-practice-optometry/guide-to-eye-conditions/dry-eye/conjunctivitis-and-eye-infections/dry-eyes-what-is-intense-pulsed-light-therapy/.

[7] Xiodan Jiang, et al., *Evaluation of the Safety and Effectiveness of Intense Pulsed Light in the Treatment of Meibomian Gland Dysfunction*, J OPHTHALMOLOGY, 2016:1910694.

> Overall, IPL has been shown to be a successful tool for managing dry eye because it treats several of the root causes of [dry eye disease] DED, including inflammation. There are multiple mechanisms of action through which IPL interrupts the inflammatory cycle that instigates and perpetuates dry eye.
>
> It is an effective standalone procedure for patients suffering from evaporative, aqueous deficient, or mixed dry eye disease etiologies. Also, it can be added to pharmacological or other treatments in a multimodality approach to manage the multifactorial signs and symptoms associated with DED.[8]

Dr. Nate Lighthizer, Associate Professor and the Associate Dean for the Northeastern State University Oklahoma College of Optometry;' has presented on the IPL therapy in the optometric practice. His presentation, attached hereto as Exhibit A and incorporated herein by this reference, provides insight into the background of IPL therapy in the optometric practice, the differences between lasers and IPL, and information on the best practices for treatment. In particular, Dr. Lighthizer described the unique usefulness of IPL in that it "breaks the vicious cycle of inflammation." He also noted how the management and therapy subcommittee of the 2017 Tear Film & Ocular Surface Society Dry Eye Workshop II (TFOS DEWS II) placed IPL as a step 2 treatment for dry eye and meibomian gland dysfunction (MGD).[9]

Efficacy. In a study published in April 2023 titled, *Efficacy of intense pulsed light therapy on signs and symptoms of dry eye disease: A meta-analysis and systematic review*, the authors found, "IPL therapy has been proven to be a safe and effective option for reducing the signs and symptoms of MGD-related DE. It is beneficial for mild to severe forms of DE; however, early treatment is considered better."[10] In looking specifically at adverse effects, the authors found that 2.5% of patients experienced mild adverse events of mild pain, localized eyelash loss, erythema, edema, hyperpigmentation, corneal/conjunctival abrasion, and hair loss at the brow and forehead as the most common symptoms but that these "symptoms went away in a short time, and no long-term or serious adverse events were noted."[11]

FDA Classification. The United States Food and Drug Administration ("FDA") has classified an IPL device for managing dry eye into class II (Special Controls).[12] Believing the action will enhance a patient's access to beneficial innovative devices, the FDA

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[8] Deepon Kar, OD, *The Role of Intense Pulsed Light in Dry Eye Management*, EYES ON EYECARE (Jan. 19, 2023), https://eyesoneyecare.com/resources/the-role-of-intense-pulsed-light-ipl-in-dry-eye-management/.
[9] *Id.*
[10] Guanghao Qin, et al., *Efficacy of Intense Pulsed Light Therapy on Sign and Symptoms of Dry Eye Disease: A Meta-analysis and Systematic Review*, INDIAN J. OPHTHALMOLOGY, 71(4): 1316-25 (2023).
[11] *Id.*
[12] 21 C.F.R. § 886.5201 (2023).

classified the IPL device as Class II instead of the automatic Class III assignment.[13] The Class II special controls for the IPL device are as follows:

(1) Clinical performance testing must evaluate adverse events and improvement of dry eye signs and symptoms under anticipated conditions of use.

(2) Thermal safety assessment in a worst-case scenario must be performed to validate temperature safeguards.

(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Physician and patient labeling must include:

(i) Device technical parameters;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) A description of the intended treatment area location;

(iv) Warnings and instructions regarding the use of safety-protective eyewear for patient and device operator;

(v) A description of intense pulse light (IPL) radiation hazards and protection for patient and operator;

(vi) Instructions for use, including an explanation of all user interface components; and

(vii) Instructions on how to clean and maintain the device and its components.

Other States: IPL is approved for use by ODs in forty-five states, including our neighboring states of Minnesota, North Dakota, Nebraska, Iowa and Wyoming.[14] South Dakota would, therefore, be far from the first state to recognize IPL use by ODs as within the scope of their practice.

CPT Codes: Intense-pulsed light does not have its own CPT code. IPL treatments are patient-paid.

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[13] *See* 21 C.F.R. § 886.5201 (2023), attached hereto as Exhibit B and incorporated herein by this reference for a more-complete explanation of the FDA decision-making process of the Class II classification through which the FDA, "classif[ies] devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B))." *Id.*

[14] American Optometric Association survey of other state associations, attached hereto as Exhibit C and incorporated herein by this reference.

(3) THE PRECISE ISSUE TO BE ANSWERED BY THE PROFESSIONAL OR OCCUPATIONAL BOARD OR COMMISSION'S DECLARATORY RULING:

The SDOS respectfully requests the Board adopt a declaratory judgment similar to the following (based upon the policy adopted by the Massachusetts Division of Professional Licensure):

> The South Dakota Board of Examiners in Optometry hereby recognizes that a licensed optometrist with appropriate skill, education and training, may utilize Intense Pulsed Light ("IPL") devices to treat dry eye disease, provided said use complies with the requirements of this policy and any other applicable regulation or law. An optometrist who provides IPL services must have proof of the optometrist's completion of appropriate training available on-site for Board inspection and upon request. Appropriate training may consist of a training program by the manufacturer, COPE-approved continuing education course, or IPL training in optometric college. An optometrist may use an IPL Devices only in a non-invasive manner and for a documented optometric purpose within the scope of the practice of "optometry" as set forth in SDCL§ 36-7-1G.L. c. 112, s. 66. An optometrist utilizing IPL shall be prepared to handle any complications from the treatment.
>
> Optometrist must ensure the IPL machine utilized meets all applicable state and federal requirements. The optometrist must retain a copy of the manufacturer's instructions for the IPL device on-site for Board inspection and upon request. An optometrist shall not use any device, setting or apparatus on any device for any purpose which is outside the scope of optometric practice in South Dakota.

Dated at Sioux Falls, South Dakota this 10th day of August, 2023.

Respectfully Submitted,

CUTLER LAW FIRM, LLP
Attorneys at Law

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Petitioner

Intense Pulsed Light (IPL) Therapy in the Optometric Practice

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Associate Dean
Director of CE
Chief of Specialty Care Clinics
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Disclosures

- Aerie Pharmaceuticals
- Biotissue
- Diopsys
- Ellex
- EyePromise
- Ivantis
- Lumenis
- Maculogix
- Nidek
- Nova Oculus
- Novartis
- Optovue
- Quantel
- Reichert
- RevolutionEHR
- Sight Sciences
- Shire
- Sun Pharma

2

Dry Eye Disease Definition

- "Dry eye is a **multifactorial** disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface"

DEWS 2007

3

DEWS 2

- Definition of dry eye:
  - *"Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles."*

4

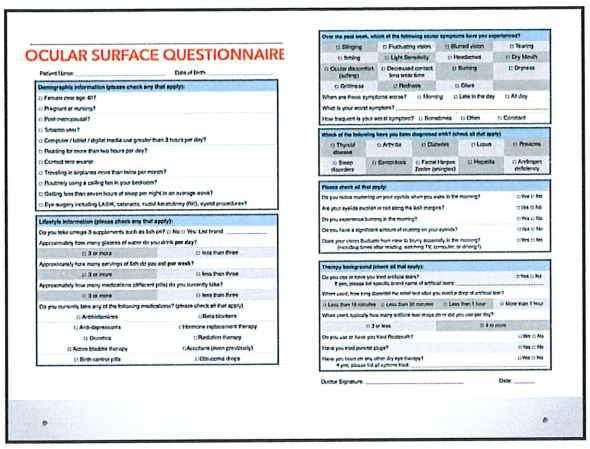
TEAR FILM INSUFFICIENCY	MEIBOMIAN GLAND OBSTRUCTION	INFLAMMATION	BACTERIAL BIOFILM
• Artificial tears • Environmental change • Punctal Plugs • Neurostim	• Blinking exercises • Moist heat compresses • Lid debridement • Thermal pulsation • Manual expression	• Cyclosporine • Lifitegrast • Topical Steroids • Topical or PO Azithromycin • PO Tetracycline • Omega fatty acids • Amniotic membranes	• Blepharo-exfoliation • Hypochlorus acid • Tea tree • Surfactant cleansers • Q-Tip Wash

5

Topical Dry Eye Therapy

Diagnostic Tests	Therapy
1. Patient questionnaire	1. Artificial Tears
2. Look for staining	2. Warm Compresses/ Bruder Mask
3. Express the glands	3. In office heat treatments
4. Meibography	4. Steroids
5. Tear Lab	5. Xiidra or Restasis
6. Inflammadry	6. Fish Oil
7. Shirmer's	7. Amniotic Membranes
	8. Autologous Serum

6



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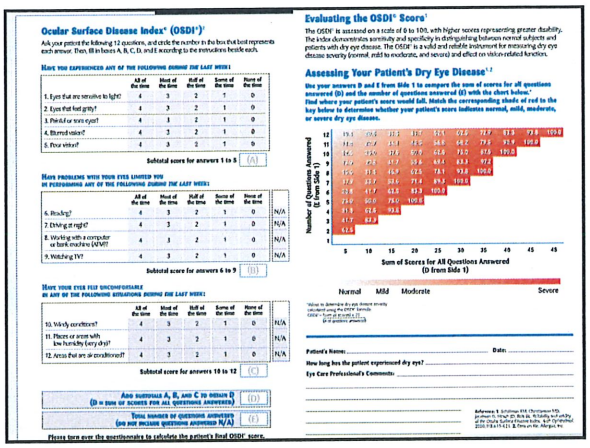

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Topical Dry Eye Therapy

Diagnostic Tests

1. Patient questionnaire
2. Look for staining
3. Express the glands
4. Meibography
5. Tear Lab
6. Inflammadry
7. NTBUT
8. Shirmer's

Therapy

1. Artificial Tears
2. Warm Compresses/ Bruder Mask
3. In office heat treatments
4. Steroids
5. Xiidra or Restasis
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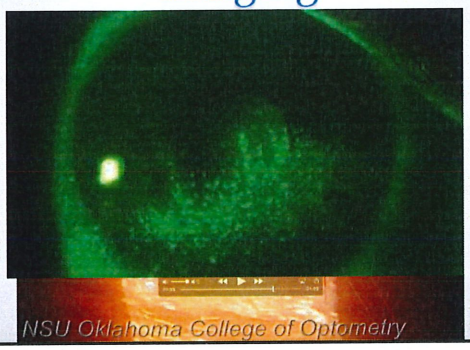
7. Amniotic Membranes
8. Autologous Serum

9

Imaging



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Topical Dry Eye Therapy

Diagnostic Tests

1. Patient questionnaire
2. Look for staining
3. Express the glands
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8. Shirmer's

Therapy

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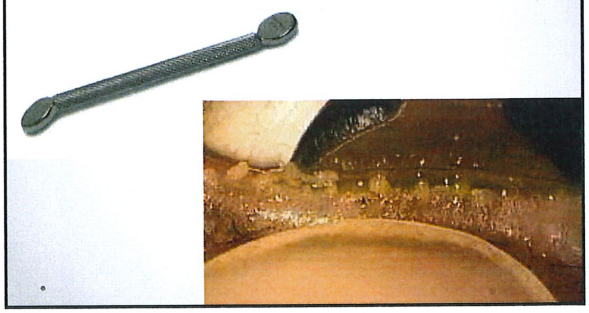
6. Fish Oil
7. Amniotic Membranes
8. Autologous Serum

11

Mastroda Paddle



12

Topical Dry Eye Therapy

Diagnostic Tests	Therapy
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2. Look for staining	2. Warm Compresses/ Bruder Mask
3. Express the glands	3. In office heat treatments
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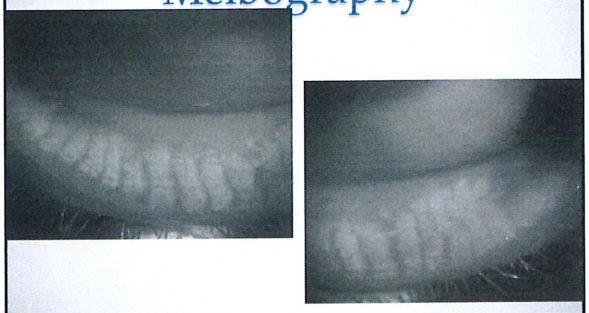
5. Tear Lab	5. Xiidra or Restasis
6. Inflammadry	6. Fish Oil
7. NTBUT	7. Amniotic Membranes
8. Shirmer's	8. Autologous Serum

13

Meibography



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OCULUS Keratograph® 5M

15

Topical Dry Eye Therapy

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6. Inflammadry	6. Fish Oil
7. NTBUT	7. Amniotic Membranes
8. Shirmer's	8. Autologous Serum

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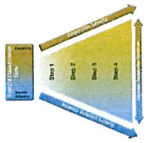
Treatment guidelines recommended by DEWS II (2017)

Step I:

- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if MGD is present, then consider lipid-containing supplements)
- Lid hygiene and warm compresses of various types



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Topical Dry Eye Therapy

Diagnostic Tests	Therapy
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2. Look for staining	2. Warm Compresses/ Bruder Mask
3. Express the glands	3. In office heat treatments
4. Meibography	4. Steroids
5. Tear Lab	5. Xiidra or Restasis
6. Inflammadry	6. IPL
7. NTBUT	7. Fish Oil
8. Shirmer's	8. Amniotic Membranes
	9. Autologous Serum

18

TEAR FILM INSUFFICIENCY	MEIBOMIAN GLAND OBSTRUCTION	INFLAMMATION	BACTERIAL BIOFILM
• Artificial tears • Environmental change • Punctal Plugs • Neurostim	• Blinking exercises • Moist heat compresses • Lid debridement • Thermal pulsation • Manual expression	• Cyclosporine • Lifitegrast • Topical Steroids • IPL • Topical or PO Azithromycin • PO Tetracycline • Omega fatty acids • Amniotic membranes	• Blepharo-exfoliation • Hypochlorus acid • Tea tree • Surfactant cleansers • Q-Tip Wash

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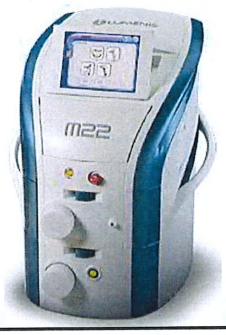
Intense Pulsed Light (IPL)

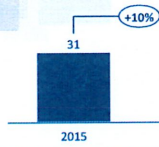


20

Over 30M Americans suffer from DED

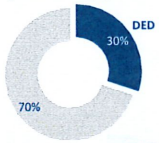
34M patients by 2025 suffer from DED

Number of Americans estimated to suffer from DED, Millions



10-30% of patients visiting Optometrists and Ophthalmologists have DED symptoms

% of patients' visits to Optometrists and Ophthalmologists with DED symptoms



Life expectancy | Cataract & refractive surgeries | Increase in screen time | Access to advanced healthcare | More advanced diagnostic tools

Source: Paulsen et al. Am J Ophthalmol. 2014; The Gallup Organization, Inc. The 2015 Gallup Study of Dry Eye Sufferers. 2015. Online poll conducted May 26- June 23, 2015; Centers for Disease Control and Prevention 2016; https://www.chuvision.com/docs/default-source/ccs-19-presentations/zloznerstein-presentation---expert-insights.pdf

21

DEWS 2

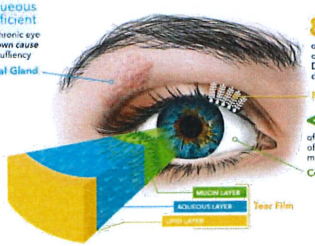
- Definition of dry eye:
  - "*Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.*"

22

MGD amounts to 86% of Dry Eye cases

14% Aqueous Deficient
of patients with chronic eye discomfort of known cause have aqueous insufficiency

Lacrimal Gland



86% MGD
of patients with chronic eye discomfort of known cause have Meibomian Gland Dysfunction as a result of blocked or damaged meibomian glands

Meibomian Glands

<1% Other
of patients with chronic eye discomfort of known cause results from lack of mucin protection

Conjuctiva

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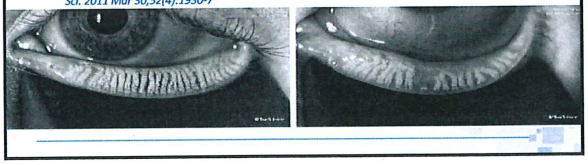
MGD

- *Meibomian gland dysfunction (MGD) is a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/ or qualitative/ quantitative changes in the glandular secretion. This may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease.* —Nesson JD, Shimazaki J, Benitez-Del-Catillo JM, et al. *The international workshop on meibomian gland dysfuntion:report of the definition and classification subcommittee.Invest Ophthalmolo Vis Sci. 2011 Mar 30;52(4):1930-7*



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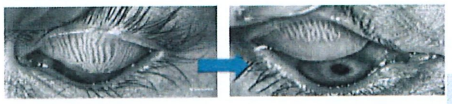
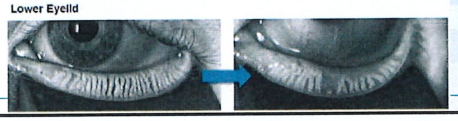
Meibomian Gland Anatomy

- Large Sebaceous glands
- Located in the tarsal plate
  - More in the upper lid (30-40)
  - Less in the lower lid (20-30)

Upper Eyelid



Lower Eyelid



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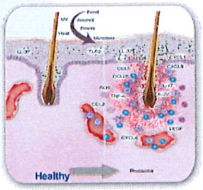
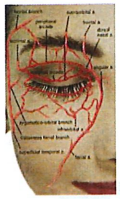
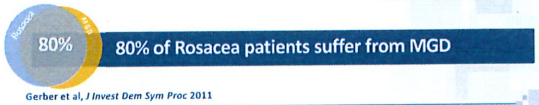
MGD is often a skin gland disease: treating rosacea is essential as it perpetuates the inflammation cycle

In rosacea, abnormal blood vessels release pro inflammatory agents



These inflammatory agents propagate to the eyelids via the orbital vasculature



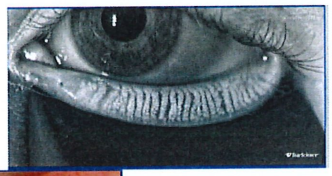


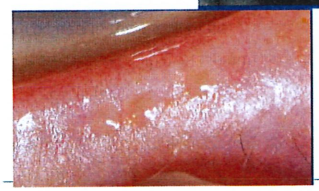
Gerber et al, *J Invest Dem Sym Proc* 2011

26

Structure and Function

- Normal Structure
- Normal Function





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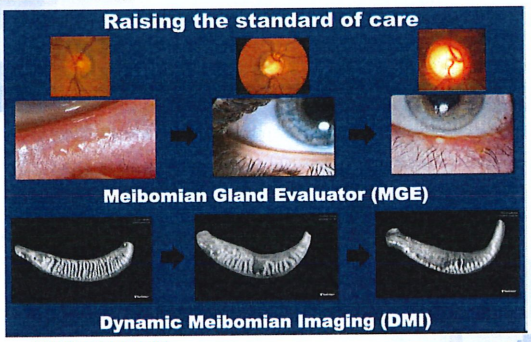
What other disease is structure before function important?



Matossian Eye Associates Copyright 2016

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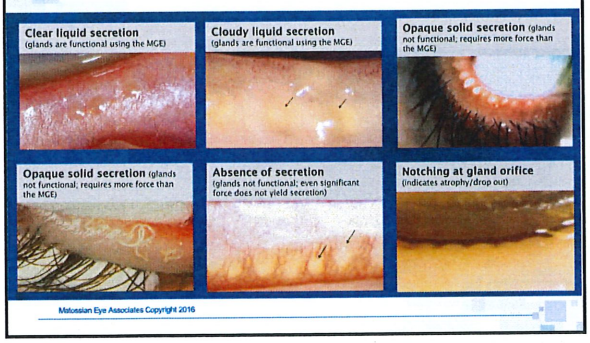
Examples of Meibomian Gland Evaluation



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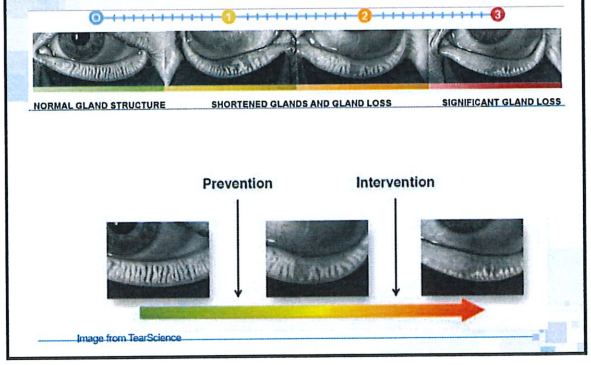
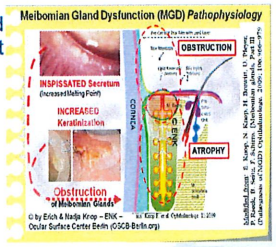
MGD is Progressive



30

Pathophysiology

- **Increased Viscosity**
  - Due to altered lipid and increased melting point
  - Bacterial colonization
- **Hyperkeratinzation**
- **Signs**
  - Lid Foam
  - Obstructed Gland Orifice
  - Lipid Crusting
  - Collarettes
  - Telangiectasia
  - Lid Margin Redness



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IPL was recognized in DEWS II for the treatment of MGD as a step 2 treatment

Treatment guidelines recommended by DEWS II (2017)

Step 1:
- Education regarding the condition, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if MGD is present, then consider lipid-containing supplements)
- Lid hygiene and warm compresses of various types

Step 2:
If above options are inadequate consider:
- Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Tea tree oil treatment for Demodex (if present)
- Tear conservation
  - Punctal occlusion
  - Moisture chamber spectacles/goggles
- Overnight treatments (such as ointment or moisture chamber devices)
- In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow)
- In-office intense pulsed light therapy for MGD
- Prescription drugs to manage DED
  - Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
  - Topical corticosteroid (limited-duration)
  - Topical secretagogues

Step 3:
If above options are inadequate consider:
- Oral secretagogues
- Autologous/allogeneic serum eye drops
- Therapeutic contact lens options
  - Soft bandage lenses
  - Rigid scleral lenses

Step 4:
If above options are inadequate consider:
- Topical corticosteroid for longer duration
- Amniotic membrane grafts
- Surgical punctal occlusion
- Other surgical approaches (eg tarsorrhaphy, s

In-office intense pulsed light therapy for MGD

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Intense Pulse Light (IPL)

- Differences between Lasers & IPL sources
- Laser Light
  - Monochromatic
  - Coherent
  - Parallel
- Intense Pulsed Light
  - Non monochromatic
  - Non coherent
  - Defocused

	Laser	Intense pulsed light (IPL)
	monochromatic: can tune out unwanted colors	polychromatic: broad spectrum visible light
	coherent: related in phase over long distances	non-coherent: phases cross each other
	collimated: beam spreads very little	divergent: beam spreads a lot
	The diode laser works on an 810nm wavelength, targeted for hair removal	IPL's work a broad spectrum of wavelengths, ranging from 450-1200nm

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IPL (Intense Pulsed Light)

- How it works
  - Emits a broad, continuous spectrum of light in the range of 515–1200 nm, with the ability to apply filters to target specific *chromophores* (i.e. melanin and hemoglobin).
  - Melanin absorption is in the 400–700 nm range
  - Blood absorption in the 900–1,200 nm range
  - Role of oxyhemoglobin
    - The light that's emitted from the flashlamp is absorbed by the oxyhemoglobin in the blood vessels → generates heat that coagulates the cells
  - Think Red's & Browns!

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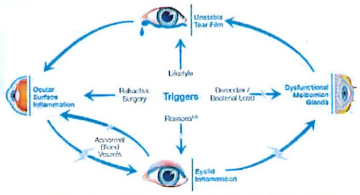
IPL breaks the vicious cycle of inflammation



- ✓ Alleviates the abnormal blood vessels that are perpetuating the inflammation
- ✓ Decreases the level of pro inflammatory mediators and inhibits the progression of the inflammation
- ✓ Reduces the osmolarity of the tear-film to normal levels
- ✓ Decreases Demodex mites that are stimulating infection and reduces bacterial load
- ✓ Restores Meibomian gland's morphology and functionality

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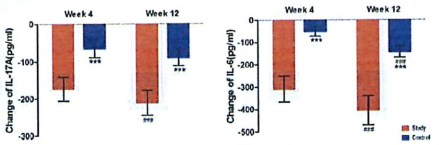
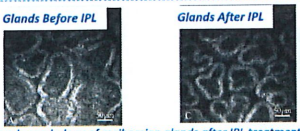
Studies demonstrate substantial improvement in inflammatory markers and gland morphology

Inflammatory Markers Decreased



Less inflammatory markers in tear samples of the treated side, compared to untreated side (Liu et al 2017)

Gland Morphology Restored



Restored morphology of meibomian glands after IPL treatment, Yin et al 2017

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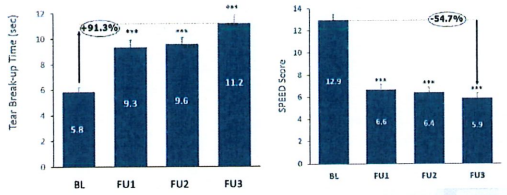
Studies show that Optima IPL significantly improves signs & symptoms of MGD

Dell et al 2017 - Results

On average, the severity of dry eye decreased from moderate to mild

TBUT improved and patients felt better



37

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Numerous clinical studies around the world prove the clear benefit of IPL

	Authors		#Pts	Main Findings
1	Karaca et al., 2018	TR	26	IPL improved Shirmer's test, TBUT, and symptoms (OSDI)
2	Arita et al., 2018a	JP	31	Symptoms and quality of tear film improved after IPL + MGX
3	Arita et al., 2018b	JP	45	Improvement in symptoms and signs in both IPL+MGX and MGY. The difference between the two arms was significant for most signs.
4	Seo et al., 2018	KR	17	Symptoms and signs of DED improved after IPL +MGX. Some signs maintained improvement after 12 months. Other signs returned to baseline after 6 months
5	Rong et al., 2018a	CN	44	Symptoms and signs of DED improved in eyes treated with IPL+MGX, and less in fellow eyes (MGX only)
	Rong et a., 2018b			TBUT and MG secretion improved 6 months after treatment in eyes treated with IPL+MGX, but not in fellow eyes (MGX only)
	Liu et al., 2017			Inflammatory markers decreased in eyes treated with IPL+MGX, and less in fellow eyes (MGX only)
6	Dell et al., 2017	US	44	Symptoms and signs of DED improved after IPL + MGX
7	Yin et al., 2017	CN	35	Gland morphology improved in pts treated with IPL, but not in pts treated daily with lid hygiene
8	Albietz & Schmid., 2017	AU	26	IPL treatment and meibomian gland expression for moderate to advanced MGD
9	Jiang et al., 2016	CN	40	Evaluation of the safety and effectiveness of IPL in the treatment of MGD
10	Vegunta et al., 2016	US	36	Combination therapy of IPL and MGX can improve DE symptoms and MG function in pts with refractory DE
11	Gupta et al.,2016	US	100	Outcomes of IPL therapy for treatment of evaporative DED
12	Toyos & Briscoe., 2016	US	16	The effects of IPL on tear osmolarity in DED
13	Caballero et al., 2016	ES	36	Effect of pulsed laser light in patients with DES
14	Craig et al., 2015	NZ	28	Prospective trial of IPL for the treatment of MGD
15	Toyos et al., 2015	US	91	IPL treatment for DED due to MGD; a 3-year retrospective study

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Who is a candidate for IPL treatment?

- Moderate to severe dry eye/ MGD/ Blepharitis
- Fitzpatrick Skin Type Scale types I-IV

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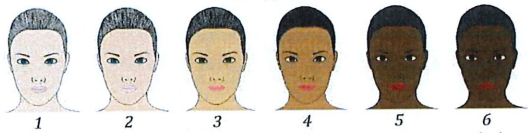
Pre treatment- Skin typing

Skin Types



1	2	3	4	5	6
Very Fair	*Fair*	*Medium*	*Olive*	*Brown*	*Black*
always burns cannot tan	*usually burns sometimes tans*	*sometimes burns usually tans*	*rarely burns always tans*	*never burns always tans*	*never burns always tans*

Patients with more pigment absorb more energy – take ethnicity into consideration – lower energy levels as you go up the Fitzpatrick scale

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Patient Selection

- Get a fully-detailed medical history-No active lupus
- Use of a medical questionnaire and informed consent form
- Exclude any lesion with malignant potential
- For any suspicion on cancerous lesion, excision biopsy may be considered
- Patients with unrealistic expectations should be identified during the consultation and discouraged

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Skin Assessment

- Tanning of all forms (sun, tanning beds) is formally contraindicated as melanin would be redistributed and migrate towards upper epidermis building a "light-blocker" to any treatment
- Also exclude self tanning lotions which give the skin a competing artificial coloration through a chemical reaction with the amino acids of the stratum corneum
- Tanned skins CANNOT be "defined" by selecting a darker skin type
- On areas with slower "de-tanning" passed the minimum solar eviction of 3-4 weeks, recommend gentle exfoliation of the area 1 week prior treatment

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Contraindications

- Treatment should not be attempted on patients with the following conditions in the treatment area:
  - Active infections
  - Dysplastic nevi
  - Significant concurrent skin conditions or any inflammatory skin conditions
  - Active cold sores, open lacerations or abrasions
  - Chronic or cutaneous viral, fungal, or bacterial diseases
  - Exposure to sun, remaining suntan or artificial tanning in the 3-4 weeks pre-op plan
  - Tattoos
- Treatment should not be attempted on patients with a history of skin cancer or pre-cancerous lesions on the treatment area

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Pre-treatment Instructions

- Do not take isotretinoin (Accutane®) for 1 month before your treatment.
- If you are tanned, please reschedule your appointment.
- Do not apply make-up or lotions on your day of treatment, or be prepared to remove them at our office.
- If you have a history of cold sores, take your prescribed medication (e.g., Valtrex, Famvir, Zovirax) on the day before, day of, and day after treatment.
- Inform the doctor before each appointment if you (1) are taking new medications or (2) have tattoos or beauty marks you do not want treated.
- Inform the doctor immediately if the area being treated feels "too hot."

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PRETREATMENT PATIENT EDUCATION

- The following should be discussed with patients prior to performing IPL treatment:
  - Results are not guaranteed.
  - Not all red and brown areas will disappear.
  - Red and brown spots removed by treatment may recur, especially with excessive sun exposure.
  - Deep wrinkle lines will not be removed by the treatment.
  - Adverse effects include redness, swelling, burning, pain, crust formation, bruising, hyper- and hypopigmentation (including striping), and scar formation.
  - Multiple treatment sessions (typically three to five) are required for optimal results.
  - Maintenance treatments are often recommended four to six months after the initial series.
- In addition, patients should be quoted a price for the treatment course.

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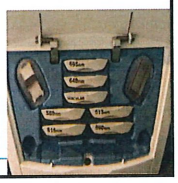
Treatment Parameters-Cut-off filters, pulse duration, fluence, and number of pulses (single, double, triple) per treatment session are chosen to assure safety and selective photothermolysis.

- Mode
  - Single Pulse
  - Double Pulse
  - Triple Pulse
- Duration (ms) per pulse
- Delay (ms)-Time delay between pulses
- Fluence (Joules/cm²)

- Cut-off Filter Wavelength
  - 695
  - 640
  - 615
  - 590
  - 560
  - 515
  - Vascular



46

Pulse Durations

- **Pulse durations** are selected to slowly heat vessels to coagulation while avoiding purpura. This allows patients to return to normal activities quickly rather than suffering from purpura for one or two weeks.
  - (PDL-Pulse Dye Laser is notorious for this)

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Energy Levels

- **Energy levels** (fluence in J/cm2) are governed by clinical response. If tissue reactions do not occur, fluence levels may be increased by 1 J/cm2 (Lumenis One) or 2 J/cm2 (VascuLight SR or Quantum IPL [Lumenis, Inc.]).
  - A good rule of thumb is to use mild to moderate erythema as the treatment end point.

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Cut-off Filters

- **Cut-off filters** are selected to optimize targeting of the chromophore while filtering out wavelengths damaging to the epidermis. These vary by skin type and target chromophore.
  - 695 nm
  - 640 nm
  - 615 nm
  - 590 nm
  - 560 nm
  - 515 nm

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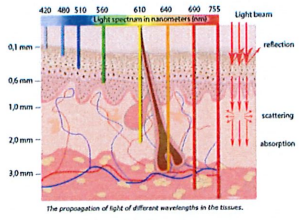
IPL – spectrum of treatment



The propagation of light of different wavelengths in the tissues.

50

ExpertFilters™	Wavelength/Spectrum	515-1200nm
	Long pass cut-off filters	515, 560, 590, 615, 640, 695 and 755*
Notch filters	Acne*	400-600 and 800-1200nm
	Vascular*	530-650 and 900-1200nm
Spot Sizes	Rectangular	15 x 35mm² and 8 x 15mm²
	Circular*	Ø 6mm
Fluence	With rectangular spots	10-35 J/cm²
	With circular spot	16-56J/cm²
Multiple Synch Pulses	Single, double or triple pulse	
Pulse Duration	4-20 ms	
Inter-pulse Delay	5-150 ms	
Repetition Rate	Up to 1 Hz	
Electrical Requirements	100-240 VAC, 12A/8A, 50/60 Hz Single Phase, Dedicated Line	

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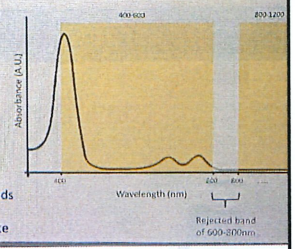
Dedicated ACNE notch filter*

- Propionibacterium acnes produce endogenous porphyrins as part of their normal metabolism
- The notch filter 400-600 & 800-1200nm is ideal for inflammatory acne:
  - When exposed at 400-600nm (with a peak at the Soret band around 400-420nm)
    - Porphyrins are excited to release Singlet Oxygen which eradicate P. Acnes
    - Superficial inflammation is reduced
  - When exposed at 800-1200nm
    - Light penetrates deeper to reach the sebaceous glands
    - The "shrinkage" of the sebaceous glands reduces the anaerobic environment necessary for the bacteria to proliferate

Porphyrin absorption spectrum (not drawn to scale)



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Treatment Aggressiveness

- Less Aggressive
  - Higher cut-off filter
  - Lower fluence
  - Higher pulses
  - Longer delay
  - Eg. 590 nm, Triple pulse, 6 m/s delay, 4 ms

- More Aggressive
  - Lower cut-off filter (meaning treat longer wavelengths and more superficial treatment)
  - Higher fluence
  - Shorter Delay
  - Fewer Pulses
  - Eg. 515 nm, single pulse, 4 ms

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Treatment protocol – OPT settings (close/on eyelid)

OPT settings: within the orbital rim (but not on eyelid margin)

Fitzpatrick Skin Type	Fluence (J/cm²)	Filter (nm)	Pulse structure	Pulse duration (msec)	Delay (msec)	Chiller
I	14-16*	590	Triple	6	50	On
II	13	590	Triple	6	50	On
III	12	590	Triple	6	50	On
IV	11	590	Triple	6	50	On
V	10	590	Triple	6	110	On

2 passes, tragus to tragus

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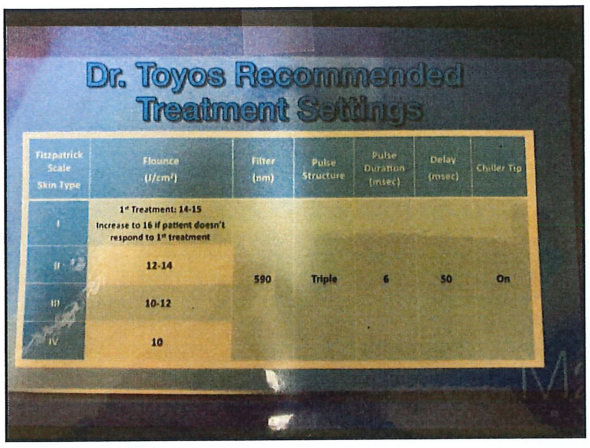

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Treatment protocol – Rosacea patients

Rosacea settings: outside the orbital rim

Fitzpatrick Skin Type	Fluence (J/cm²)	Filter (nm)	Pulse structure	Pulse duration (msec)	Delay (msec)	Chiller
I	20	560	Triple	3	15	On
II	19	560	Triple	3	20	On
III	18	560	Triple	3	25	On
IV	17	590	Triple	3	30	On
V	16	590	Triple	4	45	On

2 passes, tragus to tragus with rosacea settings

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Pearls

- A good rule of thumb is to use mild to moderate erythema as a treatment endpoint. Darkening of target pigment also represents a treatment endpoint.
- Always double-check that the settings you want to use are the settings you are using.
- As a rule, darker skin types require cautious treatment with lower energies, longer pulse durations, longer delay times, and higher-wavelength filters (e.g. 590, 615, and 640 nm).
- Utilize a white make-up pencil to cover pigment that people want to keep☺

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Optima IPL Treatment- eye shields

Corneal eye shields OR **Disposable eye sheilds**

patient eyes must be protected with fully occlusive eye shields!

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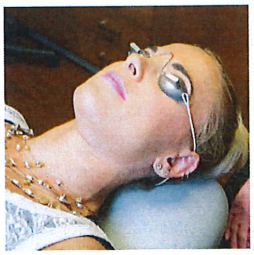
Shields

Anthonyproducts.com

Innovativeoptics.com



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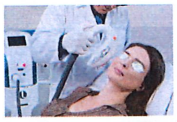
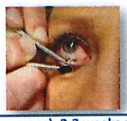
Optima IPL Treatment Process

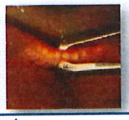
Treatment includes IPL application below eyelids, and then possible expression of the Meibomian glands

First, IPL (from ear to ear, including nose):



Then, expression (optional):





- **3-5 treatments (on average), 2-3 weeks apart**
- **Minimal discomfort.** Patients describe as: *"painless procedure"*, "spa-like treatment"

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Post Procedure

- Remove gel with tongue depressor
- Keeps treatment area clean by gently cleansing
- Keeps on moisturizing with an emollient
- Avoids direct sunlight
- Renews application of sun block SPF 30-50 until next session
- Avoids use of deodorants or fragrance as long as skin is sensitive or fragile
- Avoids scrubbing the skin

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Pitfalls

- Do not press hard on the skin when treating blood vessels. If you press hard, you will squeeze the target from the vessels.
- Do not treat near the eyebrows and other hair-bearing areas to avoid unintended hair loss.
- Remove all makeup and lipstick before starting treatment. Dark makeup and lipstick absorb significant amounts of light, which can lead to a burn.
- Do not hurry when treating vessels or pigment. Aggressive treatments can lead to burns. Remember, "You can always add more salt to the soup!"

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Complications

- Erythema (redness) and edema (swelling) of the treated area can occur
- Irritation, itching,and/or a mild burning sensation or pain similar to sunburn may occur within 48 hours of treatment.
- Pigmentary changes such as hyper pigmentation and hypo pigmentation of the skin in the treated areas can occasionally occur.
- Other known complications of this procedure include blisters, redness, pinpoint pitted scars, bruising, superficial crusting, burns, pain, and infections. These side effects are usually temporary, lasting from five to ten days but can be permanent as well.

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FAQ's

- Can I treat if patient is on doxy?
  - If low dose doxy yes, photosensitivity occurs with UV light, IPL has no UV light
- Can I use topical numbing agents?
  - No! Due to the vasoconstrictive properties this will diminish your target rendering your treatment less effective. You also need the patient to give you proper feedback
- Do I need to treat lids and do expression?
  - Periman Protocol=Yes/No. Richard Adler Protocol=Yes/No. Toyos=No/Yes
  - McGee=Depends on the patient/No-All patients improve!!
- Do I do with this before or after Thermal Pulsation (LipiFlow, Tear Care, etc)
  - Prior to
  - IPL first, Tear Care second

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Procedure Checklist

- Patient education form read and understood
- Pretreatment instructions reviewed and understood
- Informed consent signed
- Skin type identified
- Pretreatment test site confirmed with no adverse reaction
- Confirm that patient has taken prophylactic antiviral medication (if + history of HSV) and has no contraindications for treatment
- Pretreatment photograph taken
- Set up procedure tray including eye shields and masks
- Select treatment parameters
- Perform intense pulsed light treatment
- Provide verbal and written post-treatment instructions to patient
- Complete procedure note including device settings
- Subsequent treatment scheduled

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Reimbursement

- By the numbers
  - IPL
    - Cash Procedure
    - 3-5 treatments, 3-4 weeks apart
    - $750-1,500 for the treatment package
    - Disposables
      - Gel
      - Shields
      - Tongue depressors
      - Tissues
    - Instrument is approximately $60,000, no click fee

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Intense Pulsed Light (IPL) Therapy in the Optometric Practice

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5960 to subpart F to read as follows:

§ 876.5960 Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

(a) *Identification.* A computerized behavioral therapy device for treating symptoms of gastrointestinal conditions is a prescription device intended to provide a computerized version of condition-specific therapy as an adjunct to standard of care treatments to patients with gastrointestinal conditions.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must be provided to fulfill the following:

(i) Describe a model of therapy for the indicated gastrointestinal conditions;

(ii) Validate the model of therapy as implemented by the device using a clinically defined endpoint; and

(iii) Evaluate all adverse events.

(2) Software must be described in detail in the software requirements specification and software design specification. Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Labeling:

(i) Labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the device is not intended for use in lieu of a standard therapeutic intervention or to represent a substitution for the patient's medication;

(iv) Patient and physician labeling must include a warning to seek medical care if a patient has feelings or thoughts of harming themselves or others; and

(v) Physician and patient labeling must include a summary of the clinical testing with the device.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01048 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2022–N–3256]

Medical Devices; Ophthalmic Devices; Classification of the Intense Pulsed Light Device for Managing Dry Eye

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the intense pulsed light device for managing dry eye into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intense pulsed light device for managing dry eye's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 20, 2023. The classification was applicable on February 23, 2021.

FOR FURTHER INFORMATION CONTACT: Arkady Kaplan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1568, Silver Spring, MD 20993–0002, 301–796–6365, *Morris.Kaplan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the intense pulsed light device for managing dry eye as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under

section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 20, 2020, FDA received Lumenis's request for De Novo classification of the Lumenis Stellar M22. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 23, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 886.5201.[1] We have named the generic type of device intense pulsed light device for managing dry eye, and it is identified as a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—INTENSE PULSED LIGHT DEVICE FOR MANAGING DRY EYE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Tissue damage due to overheating	Thermal safety assessment, Software verification, validation, and hazard analysis, and Labeling.
Tissue damage or loss of vision due to light radiation	Clinical performance testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or burn	Thermal safety assessment, Electrical safety testing, Software verification, validation, and hazard analysis, and Labeling.
Interference with other devices	Electromagnetic compatibility testing; Software verification, validation, and hazard analysis; and Labeling.
Pain or discomfort	Clinical performance testing, and Labeling.
Failure to mitigate dry eye signs and/or symptoms	Clinical performance testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, intense pulsed light device for managing dry eye is/are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

[1] FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 886.5201 to subpart F to read as follows:

§ 886.5201 Intense pulsed light device for managing dry eye.

(a) *Identification.* An intense pulsed light device for managing dry eye is a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate adverse events and improvement of dry eye signs and symptoms under anticipated conditions of use.

(2) Thermal safety assessment in a worst-case scenario must be performed to validate temperature safeguards.

(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Physician and patient labeling must include:

(i) Device technical parameters;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) A description of the intended treatment area location;

(iv) Warnings and instructions regarding the use of safety-protective eyewear for patient and device operator;

(v) A description of intense pulse light (IPL) radiation hazards and protection for patient and operator;

(vi) Instructions for use, including an explanation of all user interface components; and

(vii) Instructions on how to clean and maintain the device and its components.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01049 Filed 1–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000, 1002, 1010, 1020, 1030 and 1050

[Docket No. FDA–2018–N–3303]

RIN 0910–AH65

Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending and repealing parts of the radiological health regulations covering recommendations for radiation protection during medical procedures, certain records and reporting for electronic products, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products. The Agency is taking this action to clarify and update the regulations to reduce regulatory requirements that are outdated and duplicate other means to better protect the public health against harmful exposure to radiation emitting electronic products and medical devices.

DATES: This rule is effective February 21, 2023.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert Ochs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3680, Silver Spring, MD 20993, 301–796–6661, email: *Robert.Ochs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This final rule amends and repeals certain regulations for radiation emitting electronic products and medical devices because the FDA has identified the regulations as being outdated and duplicative of other means for reducing radiation exposure to the public. The Agency is updating the regulations to amend or repeal regulations that are outdated and otherwise clarify requirements for protecting the public health against radiation exposure from specific electronic products and medical devices. The regulations being finalized for amendment or repeal are the radiation protection recommendations for specific uses, records and reporting requirements for electronic products, applications for variances, and performance standards for diagnostic x-ray systems and their major components, laser products, and ultrasonic therapy products.

B. Summary of the Major Provisions of the Final Rule

This final rule updates FDA's radiological health regulations to amend or repeal the following provisions:

- Repeal the radiation protection recommendations that have become outdated and unnecessary;
- Removing or reducing some of the annual reports and test record

SDOS
SOUTH DAKOTA OPTOMETRIC SOCIETY

IPL USE NATIONALLY FOR DED TREATMENT BY OPTOMETRISTS

SOURCE: THE AMERICAN OPTOMETRIC ASSOCIATION

Gray states have neither law nor rule specifically allowing IPL use, but ODs are using it for DED treatment. Green states report ODs using IPL for treatment of DED.