



December 26, 2016

Tear Film Innovations, Inc.
John Slate
Vice President, R&D
12625 High Bluff Drive, Suite 107
San Diego, CA 92130

Re: K172645
Trade/Device Name: iLux System
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: November 28, 2017
Received: November 29, 2017

Dear John Slate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172645

Device Name

iLux System

Indications for Use (Describe)

The iLux System is indicated for the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY – K172645

Submitter Information

Company Name:	Tear Film Innovations, Inc.
Company Address:	12625 High Bluff Drive, Suite 107 San Diego, CA 92130
Company Phone:	(844) 458-9776
Company Facsimile:	N/A
Contact Person:	John Slate PhD Vice President of Research and Development jslate@tearfilm.com
Date:	December 12, 2017

Device Identification

Device Trade Name:	iLux® System
Common Name:	N/A
Classification Name(s):	Eyelid Thermal Pulsation System
Classification Regulation(s):	21 CFR 886.5200
Device Class:	Class II
Product Code(s):	ORZ
Advisory Panel:	Ophthalmic

Identification of Predicate Devices

The iLux System is substantially equivalent to the following device, which was cleared for commercial distribution in the United States:

- The LipiFlow Thermal Pulsation System manufactured by TearScience, Inc. and cleared for commercial distribution under 510(k): K133127.

Device Description

The iLux System is a medical device intended for use by Licensed Eye Care Professionals (ECP) to apply localized heat and pressure therapy to adult patients' lower and/or upper eyelids. The iLux System consists of a hand-held Instrument coupled to a single-use sterile Disposable component that is positioned behind the eyelid. The iLux System allows the ECP to view the eyelid margin through a magnifier, then warm the eyelid tissue to a target range of 40 to 42 °C to melt the meibum blocking the gland orifices and then apply compression to the eyelid to express

the melted meibum through the orifices. The inner eyelid temperature and the amount of force applied to the eyelid are both displayed on the Instrument allowing the clinician to titrate the ideal amount of heating and compression to optimize unclogging of the blocked glands.

The Disposable is a sterile, single-use component that is attached to the iLux Instrument. It includes all parts intended to contact the patient's eyelid.

The iLux Instrument is a handheld device that allows the ECP to view, heat, and compress the portion of the eyelid that is in contact with the Disposable. The source of heating is lime-green and infrared optical radiation produced by LEDs in the Instrument. The iLux Instrument is powered by a rechargeable lithium ion battery. The software Level of Concern is Moderate.

Ancillary accessories include the charging stand with AC power supply.

Indications for Use

The iLux System is indicated for the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye.

Comparison of Technological Characteristics with Predicate Device

Comparison Feature	The iLux® System Tear Film Innovations Inc.	LipiFlow® Thermal Pulsation System TearScience, Inc.
Single Patient Use?	Yes	Yes
Provided Sterile?	Yes	Yes
Method of sterilization, SAL (Pertinent to Disposable)	Ethylene Oxide, SAL 10 ⁻⁶	Gamma, SAL 10 ⁻⁶
Biocompatibility Testing (ISO 10993-1), of Patient Contact Materials (Pertinent to Disposable)	Yes, Silicone Cover	Yes, Silicone and UV Cured Adhesive
Packaging (Pertinent to Disposable)	Sealed Pouch	Sealed Tray
Controller Component Characteristics	Instrument, Model 2020	Console, Model LFTP-1000
Operating Orientation	Handheld	Desktop
Temperature accuracy	+/- 1.0°	+/- 0.5°
Target temperature range	40 to 42 °C	40 to 43 °C
Maximum Inner Eyelid Surface temperature limit	44 °C	44 °C
Maximum Outer Eyelid Surface temperature limit	45 °C	No outer eyelid sensor or temperature limit
Heat Source	LEDs (lime-green and IR wavelengths)	Resistive (plastic) electric heater
Rate of heating (time to target temperature)	15 to 50 seconds	10 to 60 seconds
Glands can be viewed during procedure	Yes, through magnifier	Not visible

Comparison Feature	The iLux® System Tear Film Innovations Inc.	LipiFlow® Thermal Pulsation System TearScience, Inc.
Pressure Control	Manual: Eye Care Professional determines (based on patient feedback and direct viewing of glands)	Automatic: Pre-programmed with some adjustment allowed by Eye Care Professional
Pressure type	Compression, repeated as necessary	Massage
Treatment of upper and lower eyelids	Sequential	Concurrent
Treatment Time	Typically, 8-12 minutes	12 minutes
Software	Yes	Yes
Power Source	Batteries, DC Power	AC Power
Safety per IEC 60601-1 & -2	Meets Requirements	Meets Requirements

Summary of Testing Performed

A program of design verification and validation testing was performed that includes the following:

- Biocompatibility
- Sterility and EO Residual
- Packaging Integrity (i.e., Sterile Barrier)
- Transportation
- Optical Radiation Safety
- Electromagnetic Compatibility and Electrical Safety
- Stability/Shelf-Life
- Performance/Functionality/Safety
- Software
- Clinical performance

Results of the evaluations demonstrate that the iLux System met the safety and performance requirements as it relates to its indication for use.

Clinical Study Summary

A clinical study was conducted to verify that the technological differences between the iLux System and the LipiFlow System (i.e., predicate) do not adversely affect safety and effectiveness as it relates to indications for use.

142 subjects (284 eyes) participated in the study, comprised of 101 women and 41 men, ages 19 to 86 years (mean = 54.9 ± 15.3 years). The subjects were randomized for treatment, in a 1:1 ratio into the treatment groups (i.e., iLux, LipiFlow).

The iLux arm of the study met the criteria for non-inferiority relative to the LipiFlow arm for the co-primary effectiveness endpoints – Meibomian Gland Score (MGS) and Tear Break-Up Time (TBUT) and the secondary effectiveness endpoint – Ocular Surface Disease Index (OSDI).

- MGS improved significantly from baseline in both treatment groups at both week 2 and week 4. MGS improvements did not differ significantly between the two treatment groups at either follow-up visit.

- TBUT improved significantly from baseline in both treatment groups at both week 2 and week 4. TBUT improvements did not differ significantly between the two treatment groups at either follow-up visit.
- OSDI improved significantly from baseline in both treatment groups at both week 2 and week 4. OSDI improvements did not differ significantly between the two treatment groups.

There was a total of four device/procedure-related adverse events (AEs) of any type. All AEs were observed in the iLux arm and consisted of: burning sensation without skin findings (n=2), petechial hemorrhage in lower lids (n=1), and transient decrease in BSCVA with findings of superficial punctate keratitis (n=1). All were self-limited, transient, and resolved without sequelae.

The secondary safety endpoints were: 1) discomfort and pain, and 2) changes from baseline for ocular surface staining, Intraocular pressure (IOP), and BSCVA (Best Spectacle Corrected Visual Acuity).

- Pain scores were significantly lower from the baseline for both treatment groups, immediately post-treatment, and at day 1, week 2 and week 4. Immediately post-treatment, the mean pain score was significantly lower for the LipiFlow arm than for the iLux. Pain scores did not differ significantly between the two treatment groups at day 1, week 2, or week 4.
- Discomfort scores were significantly lower from the baseline for both treatment groups, immediately post-treatment, and at day 1, week 2 and week 4. Immediately post-treatment, the mean discomfort score was significantly lower for the LipiFlow arm than for the iLux. Improvements in discomfort scores did not differ significantly between the two treatment groups at day 1 or week 2. At week 4, however, the discomfort score was significantly lower for the iLux group.
- Ocular surface staining was significantly increased immediately following treatment in both treatment groups. At day 1, week 2, and week 4, the ocular surface staining significantly reduced relative to baseline in both treatment groups however did not differ significantly between the two treatment groups.
- No clinically significant changes in IOP were observed immediately post-treatment or throughout follow-up in either treatment group.
- BSCVA was significantly reduced relative to baseline immediately post-treatment in both treatment groups but not to a clinically meaningful level. At week 2 and week 4, BSCVA was significantly improved relative to baseline in both treatment groups, but the change was not different between treatment groups.

Conclusions Drawn from Nonclinical & Clinical Evaluation

The results of the evaluation demonstrate that the iLux System is substantially equivalent to the LipiFlow Thermal System as it pertains to the indications for use and device performance.