October 22, 2019

TearScience Inc.
Ms. Michelle Ricafort
Sr. RA Program Lead
1700 East St. Andrew Place
Santa Ana, CA 92705

Re: K192623
Trade/Device Name: LipiFlow® Thermal Pulsation System (Console Model LFTP-1000, Cable Model CBL-2000, Activator II (Disposable) Model LFD-2000, Activator II (Disposable) Model LFD-2100)
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: September 20, 2019
Received: September 23, 2019

Dear Ms. Ricafort:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192623

Device Name

LipiFlow® Thermal Pulsation System
(Component Models LFTP-1000, LFD-2000, LFD-2100 and CBL-2000)

Indications for Use *(Describe)*

The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

PREPARATION DATE:	September 20, 2019
APPLICANT:	TearScience, Inc. 510 Cottonwood Drive Milpitas, CA 95305 Tel: (714) 247-8434 Fax: (714) 247-8676
CONTACT PERSON:	Michelle Ricafort Sr. Regulatory Affairs Program Lead
DEVICE TRADE NAME:	LipiFlow® Thermal Pulsation System • *Console Model LFTP-1000* • *Cable Model CBL-2000* • *Activator II (Disposable) Model LFD-2000* • *Activator II (Disposable) Model LFD-2100*
CLASSIFICATION NAME:	Eyelid Thermal Pulsation System
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.5200
PRODUCT CODE:	ORZ
PREDICATE DEVICE:	LipiFlow® Thermal Pulsation System Class II under 21 CFR 886.5200 Applicant: TearScience, Inc. Cleared under K161357 on November 4, 2016 • *Console Model LFTP-1000* • *Cable Model CBL-2000* • *Activator II (Disposable) Model LFD-2000*

The following 510(k) Summary is submitted in accordance with 21 CFR 807.92.

DEVICE DESCRIPTION:

The LipiFlow® Thermal Pulsation System is used by a physician in an in-office procedure for patients with chronic cystic conditions of the eyelids to provide controlled heat to the inner eyelid surface, close to the location of the meibomian glands, and intermittent pressure to the outer eyelid to facilitate release of lipid from the cystic meibomian glands. The LipiFlow® System is comprised of a physician interface (Control component labeled as "Console") and a patient interface (Disposable component labeled as "Activator II"). The Console provides the electrical power, user interface, treatment monitoring, treatment control and safeguard circuitry used for controlling the heat and pressure applied to the patient's eyelids with the Activator II Disposable.

This 510(k) submission is for modification of the proposed Activator II Disposable (Model LFD-2100) and labeling changes to the predicate Activator II (Model LFD-2000). The proposed devices have the same intended use, indications for use and fundamental scientific technology as the legally marketed predicate device. The proposed Activator II Model (LFD-2100) is the same as the predicate Activator II Models (LFD-2000) except for the following:

- Eye Cup Assembly Redesign: the Activator II eye cup, which consists of the bladder and substrate, will be redesigned to allow the eye cup to be manufactured as a single versus seven-piece molded bladder assembly while still attaching to the lid warmer in the same location.
- Back Surface Overmold Redesign: the back surface overmold of the lid warmer will be redesigned to accommodate the modified Single Piece Eye Cup. The design change will be limited to the removal of the t-extrusion in the Z-direction used to hold the original Eye Cup in position.
- The material for the non-patient contact bladder substrate will be changed from Valox (PBT) to polycarbonate.

The labeling for the predicate Activator II Model (LFD-2000) will also be updated to replace special storage and handling conditions with the statement: "Store at room temperature".

Compared to the predicate Activator II Model, the patient interface portion of the proposed Activator II Model is identical in patient-contact materials, electrical safety, packaging, sterility, shelf-life, method of preventing re-use, and temperature and pressure performance and safety. The proposed Activator II Model (LFD-2100) will remain fully backwards compatible with the current LipiFlow® Console and Semi-permanent Cable. There are no changes to the Console and Cable from the predicate device.

INTENDED USE:

The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

The Intended Use and Indications for Use remain unchanged.

TECHNOLOGICAL CHARACTERISTICS:

The LipiFlow® Thermal Pulsation System with proposed Activator II model has the same fundamental scientific technology as the predicate device, as described in K161357. The technological characteristics between the proposed Activator II Model and the predicate Activator II Model remain unchanged except for the design and material changes described in the Device Description section above. The similarities and differences in technological characteristics are described below.

Similarities: The proposed subject device (LipiFlow® System with proposed Activator II model LFD-2100) and the predicate Activator II device (LFD-2000) have the following same design features:

- Both devices have the same principle of operation.
- Both devices have a single-use, hermetically sealed, biocompatible Disposable component, which has the same design features for temperature safety, pressure safety, mechanical safety, biocompatibility, sterility and method to prevent re-use.

- Both devices are backwards compatible with the current LipiFlow Console (LFTP-1000). The console remains unchanged.
- Both devices use a semi-permanent Cable (Model CBL-2000) to join the patient interface (Disposable) to the physician interface (Console) that has the same electrical and pneumatic design requirements. The Cable remains unchanged.
- Both devices have a Control component with the same treatment hardware, treatment control, temperature and pressure specifications, safety features, device self-tests, software user interface and touchscreen display.
- Both devices comply with the same performance standards for electrical safety and electromagnetic compatibility (EMC).

Differences: The differences between the subject device of this submission (LipiFlow® System with modified Activator II model LFD-2100) and the predicate Activator II device (Model LFD-2000) include:

- The Activator II assembly was redesigned as follows:
  - The Eye Cup (bladder and substrate) assembly redesign will allow the Eye Cup to be manufactured as a single molded assembly (compared to a seven-piece molded bladder assembly) while still attaching to the lidwarmer in the same location.
  - The material for the non-patient contact bladder substrate will be changed from Valox to polycarbonate.
  - The Back Surface Overmold was redesigned to accommodate the proposed Single Piece Eye Cup. The design change will be limited to the removal of the t-extrusion in the Z-direction used to hold the original Eye Cup in position.
- The labeling for the predicate Activator II Model (LFD-2000) was also updated to replace special storage and handling conditions with the statement: “Store at room temperature”.

Table 1 provides a comparison of the characteristics of the Activator II (Model LFD-2000), the predicate device and the subject modified Activator II devices (Models LFD-2000 and LFD-2100).

TABLE 1: SIMILARITIES AND DIFFERENCES BETWEEN CLEARED PREDICATE DEVICE AND MODIFIED DEVICES

Attribute	Cleared Predicate Device LipiFlow® System with Activator II (Model LFD–2000)	Subject Modified Devices LipiFlow® System with Activator II (Models LFD-2000 and LFD-2100)
510(K) Number	K161357	This application
Manufacturer	TearScience, Inc.	Same
Class	Class II	Same
Product Code	ORZ	Same
Classification Section	CFR 886.5200	Same

TABLE 1: SIMILARITIES AND DIFFERENCES BETWEEN CLEARED PREDICATE DEVICE AND MODIFIED DEVICES

Attribute	Cleared Predicate Device LipiFlow® System with Activator II (Model LFD–2000)	Subject Modified Devices LipiFlow® System with Activator II (Models LFD-2000 and LFD-2100)
Intended Use	The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.	Same
Principle of Operation	Controlled heat and pressure therapy focused on the meibomian glands in the eyelids through a Disposable eyepiece component (Activator or Activator II) that functions with a Control component (Console)	Same
Disposable Component	Single-use, hermetically sealed, biocompatible polycarbonate and silicone eyepiece that is connected through electrical wiring cable and air tubing to the Control component (Console)	Same
Cable	CBL-2000	Same
User Pressure Level Control	Pressure level adjustable from approximately 70% to 100%, as needed for patient comfort	Same
Shelf-Life	Four years	Same
Treatment Time Specification	12 minutes	Same
Storage Conditions	20° to 25°C with short term excursions of <72 hours with temperatures between 5°C and 38°C	Same
Transport Conditions	5°C to 60°C	Same
Storage Conditions Labeling	20° to 25°C with short term excursions of <72 hours with temperatures between 5°C and 38°C	Store at room temperature
Transport Conditions Labeling	5°C to 60°C	Store at room temperature
Eye Cup Assembly Design	Seven-piece molded assembly	One-piece molded assembly

SUBSTANTIAL EQUIVALENCE

The subject Activator II devices (Models LFD-2000 and LFD-2000) is substantially equivalent to the predicate Activator II device (Model LFD-2000) which was cleared under premarket notification K161357, in terms of:

- Indications for use
- Intended use
- Fundamental technological characteristics

SUMMARY OF PERFORMANCE TESTING:

Performance testing was conducted to demonstrate substantial equivalence of the proposed Activator II, Model LFD-2100, to the predicate Activator II (Model LFD-2000) devices, and to validate continued conformance to the following *special controls* for an eyelid thermal pulsation system per 21 CFR 886.5200. No animal or clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology when compared to the predicate device.

5) Performance testing demonstrates that the LipiFlow® System using the proposed Activator II Model (LFD-2100) conforms to the same electrical safety and EMC performance standards as for the predicate Activator II Model (LFD-2000).

6) Performance testing shows that the LipiFlow® System using the proposed Activator II Model (LFD-2000) and Cable has equivalent temperature and pressure performance and safeguard functions, including during fault conditions, as the predicate Activator models. The modified device meets the same design requirements as the predicate device based on known safe and effective temperature and pressure specifications, previously validated in bench, animal and clinical studies of the LipiFlow® System.

7) The packaging, sterility and shelf-life for the proposed Activator II Model are the same as for the predicate Activator Model. The proposed Activator II Model meets the same performance standards for sterility and shelf-life as the predicate Activator II Model.

8) The patient-contacting materials for the proposed Activator II Model are the same as for the predicate Activator II Models. The non-patient-contacting materials for the proposed Activator II Model (LFD-2100) will be changed from Valox to polycarbonate from the predicate Activator II Model (LFD-2000). The modified Activator II Model (LFD-2100) meets the same biocompatibility performance standards as the predicate Activator II Model.

Performance testing shows that the proposed Activator II Model does not raise new questions of safety and effectiveness, and does not adversely affect safety and effectiveness of the device.

CONCLUSIONS:

The LipiFlow® System with proposed Activator II Model (LFD-2100) and labeling changes to the Activator II Model (LFD-2000) have the same intended use, indications for use, and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the subject devices in this 510(k) are at least as safe and effective as the legally marketed LipiFlow® System using the predicate Activator II Model (LFD-2000). Therefore, the LipiFlow® System with proposed Activator II (Models LFD-2000) and is substantially equivalent to the predicate device.