



Food and Drug Administration
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November 4, 2016

TearScience, Inc.
Ms. Christy Coleman
Vice President, Clinical, Quality and Regulatory Affairs
5151 McCrimmon Parkway
Suite 250
Morrisville, NC 27560

Re: K161357
Trade/Device Name: Lipiflow[®] Thermal Pulsation System
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: October 4, 2016
Received: October 5, 2016

Dear Ms. Coleman:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Kesia Alexander

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)

Device Name

LipiFlow® Thermal Pulsation System
(Component Models LFTP-1000, LFD-1000, LFD-1100, LFD-2000 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.

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510(k) SUMMARY

- PREPARATION DATE:** September 26, 2016
- APPLICANT:** TearScience, Inc.
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560
Tel: (919) 467-4007
Fax: (919) 467-3300
- CONTACT PERSON:** Christy Coleman, OD, MPH
Vice President, Clinical, Quality & Regulatory Affairs
- DEVICE TRADE NAME:** LipiFlow® Thermal Pulsation System
- *Console Model LFTP-1000*
 - *Activator (Disposable) Models LFD-1000, LFD-1100 and LFD-2000 with Cable Model CBL-2000*
- 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 DEN100017 on June 28, 2011
- *Handheld Control System Model LFH-1000 and*
 - *Disposable Model LFD-1000*
- Cleared under K112704 on December 19, 2011 (corrected letter received January 12, 2012)
- *Console Model LFTP-1000 and*
 - *Activator (Disposable) Model LFD-1000*
- Cleared under K133127 on December 23, 2013
- *Console Model LFTP-1000 and*
 - *Activator (Disposable) Models LFD-1000 and LFD-1100*

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) and a patient interface (Disposable component). The Control component (labeled as 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 by the Disposable component (labeled as Activator).

This 510(k) submission is for the device modification of new model of the Disposable component (labeled Activator II, Model LFD-2000), a new semi-permanent Cable (Model CBL-2000), and a hardware and software update to the Control component (labeled as Console, Model LFTP-1000). The modified LipiFlow® System has the same intended use, indications for use and fundamental scientific technology as the legally marketed predicate device.

The new Activator II model (LFD-2000) is the same as the predicate Activator models (LFD-1000 and LFD-1100) except that the electrical and pneumatic connection point is moved closer to the patient interface. This allows the disposable portion of the device to be smaller and less wasteful. The predicate Activator models include a combined patient interface and permanently attached cable, which is connected to the Console and disposed of after each treatment. Conversely, the patient interface of the new Activator II model is used with a new semi-permanent Cable, which connects the Activator II to the Console but is not disposed of after treatment. Compared to the predicate Activator models, the patient interface portion of the new Activator II model is identical in shape, size, patient contact materials, electrical safety, packaging, sterility, shelf-life, method of preventing re-use, and temperature and pressure performance and safety.

The LipiFlow® Console hardware was updated with a new equivalent computer to address computer obsolescence in the predicate device. To support the new computer, the Console was updated to a new Operating System and the software application was modified to support the hardware-specific driver differences in the Operating Systems.

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 have not changed.

TECHNOLOGICAL CHARACTERISTICS:

The modified LipiFlow® Thermal Pulsation System has the same fundamental scientific technology as the predicate device, as described in DEN100017, K112704 and K133127. Most of the technological characteristics of the LipiFlow® System remain unchanged from the predicate device. The similarities and differences in technological characteristics are described below.

Similarities:

The modified device and the predicate device 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 use a Cable to join the patient interface (Disposable) to the physician interface (Console) that has the same electrical and pneumatic design requirements.

- 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 new Activator II (Model LFD-2000) with the new semi-permanent Cable (Model CBL-2000) and the predicate Activator models (LFD-1000 and LFD-1100) include:

- Activator II does not have a permanently attached cable for air tubing and electrical wiring. Activator II has a new electrical and pneumatic connector located behind the patient interface area that attaches to the new semi-permanent Cable. The single-use fuse that disables the Disposable component after treatment to prevent re-use was moved from the cable connector in the predicate Activator model to the Activator II.
- The new Cable is not disposable; it is semi-permanent and designed and tested for over 2,500 uses. A locking clip was added to the Cable connector to the Console to prevent accidental disposal of the Cable and to keep the connection with the Console secure. An electrical switch was added to the Cable connector to the Console, which when pressed will electrically disconnect the Cable from the Console facilitating self-test and troubleshooting system error messages. The Cable has a new electrical and pneumatic connector to attach to the Activator II. The Cable has three additional electrical conductors needed to detect when the Activator II is connected and to deactivate the Activator II when treatment is complete to prevent re-use. A new Cable holder was designed to store the Cable on the Console when not in use.

The differences between the modified Console and the predicate Console include:

- The modified Console hardware has a new equivalent computer because the computer in the predicate device became obsolete.
- The modified Console utilizes off-the-shelf Microsoft Windows 7 Embedded Operating System with drivers to support a new computer; whereas, the predicate device utilizes off-the-shelf Microsoft Windows XP Embedded Operating System.
- The modified LipiFlow[®] software application has been updated from the predicate software to support the hardware-specific driver differences in the Operating Systems.

PERFORMANCE TESTING:

Performance testing was conducted to demonstrate substantial equivalence of the modified LipiFlow[®] System to the predicate LipiFlow[®] System, and to validate continued conformance to the following *special controls* for an eyelid thermal pulsation system per 21 CFR 886.5200.

- 1) Performance testing demonstrates that the modified LipiFlow[®] System conforms to the same electrical safety and EMC performance standards as for the predicate device.

- 2) Performance testing shows that the modified LipiFlow[®] System has equivalent temperature and pressure performance and safeguard functions, including during fault conditions, as the predicate device. 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.
- 3) The packaging, sterility and shelf-life for the new Activator II model are the same as for the predicate Activator models. The new Activator II model meets the same performance standards for sterility and shelf-life as the predicate Activator models.
- 4) The patient contact materials for the new Activator II model are the same as for the predicate Activator models. Therefore, the new Activator II model meets the same biocompatibility performance standards as the predicate Activator models.
- 5) Performance testing shows that the device modifications do not raise new questions of safety and effectiveness, and do not adversely affect safety and effectiveness of the device.

Furthermore, software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern because the software is an accessory to a medical device that has a moderate level of concern. Prior to the mitigation of hazards, a failure of the device could result in minor injury to the patient or user.

CONCLUSIONS:

The modified LipiFlow[®] System has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the modified LipiFlow[®] System is at least as safe and effective as the legally marketed LipiFlow[®] System. Therefore, the modified LipiFlow[®] System is substantially equivalent to the predicate device.