



Food and Drug Administration  
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Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

TearScience, Inc.  
c/o Christy Stevens, O.D.  
Vice President, Clinical and Regulatory Affairs  
1101G Aviation Parkway  
Morrisville, NC 27560

**JUN 28 2011**

Re: K093937  
LipiFlow® Thermal Pulsation System  
Evaluation of Automatic Class III Designation  
Regulation Number: 21 CFR 886.5200  
Regulation Name: Eyelid Thermal Pulsation System  
Regulatory Classification: Class II  
Product Code: ORZ  
Dated: August 6, 2010  
Received: August 9, 2010

Dear Dr. Stevens:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the LipiFlow® Thermal Pulsation System, a prescription device under 21 CFR Part 801.109 that is indicated 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. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the LipiFlow® Thermal Pulsation System and substantially equivalent devices of this generic type into class II under the generic name, eyelid thermal pulsation system.

FDA identifies this generic type of device as:

An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used 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 system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976

(the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the act, FDA issued an order on July 12, 2010 automatically classifying the LipiFlow<sup>®</sup> Thermal Pulsation System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On August 9, 2010, FDA filed your petition requesting classification of the LipiFlow<sup>®</sup> Thermal Pulsation System into class II. The petition was submitted under section 513(f)(2) of the act. In order to classify the LipiFlow<sup>®</sup> Thermal Pulsation System into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, together with the information you provided in interactive review and in response to additional information requests, FDA has determined that the LipiFlow<sup>®</sup> Thermal Pulsation System, indicated 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, can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

**Table – Potential Risks and Mitigations**

<b>Identified Potential Risk</b>	<b>Recommended Mitigation Measures</b>
Infection	Sterility and Shelf Life Testing
Adverse tissue reaction	Biocompatibility
Electrical shock	Electrical Safety Testing
Electromagnetic interference	Electromagnetic Compatibility (EMC) Testing; Labeling
Thermal damage	Temperature Performance Testing
Mechanical damage	Pressure Performance Testing
Malfunction	Non-clinical and Clinical Performance Testing
User error	Labeling

In addition to the general controls of the FD&C Act, the LipiFlow<sup>®</sup> Thermal Pulsation System is subject to the following special controls: (1) Appropriate analysis/ testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation; (2) Design, description, and performance data should validate safeguards related to the temperature and pressure aspects of the device, including during fault conditions; (3) Performance data should demonstrate the sterility of patient-contacting components and the shelf-life of these components; (4) The device should be demonstrated to be biocompatible; and (5) Performance data should demonstrate device safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit to FDA a premarket notification containing

information on the eyelid thermal pulsation system they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact [REDACTED] at (301) 796-[REDACTED].

Sincerely yours,

A handwritten signature in cursive script, which has been partially obscured by a black redaction box.

Jonette Foy, Ph.D.  
Acting Deputy Director  
for Science and Regulatory Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health