



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Zeltiq™ Aesthetics, Inc.
c/o Mr. Louis-Pierre Marcoux
Regulatory Affairs Manager
4698 Willow Road
Pleasanton, California 94588

Re: K080521

SEP 15 2010

Evaluation of Automatic Class III Designation
Zeltiq™ Dermal Cooling Device
Regulation Number: 21 CFR 878.4340
Classification: Class II
Product Code: OOK

Dear Mr. Marcoux:

This letter corrects our classification letter of August 24, 2010.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Zeltiq™ Dermal Cooling Device indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of the subcutaneous fat layer, subject to prescription use as per 21 CFR 801.109. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Zeltiq™ Dermal Cooling Device, and substantially equivalent devices of this generic type into class II under the generic name, Contact Cooling System for Aesthetic Use.

FDA identifies this generic type of device 21 CFR 878.4340 as:

A Contact Cooling Device for Aesthetic Use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells for non-invasive aesthetic use.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the 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 21 CFR 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device type under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device type. This classification shall be the initial classification of the device type. 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.

On October 13, 2009, FDA filed your petition requesting classification of the Zeltiq Dermal Cooling Device into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on October 7, 2009 automatically classifying the Zeltiq™ Dermal Cooling Device 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, which was subsequently reclassified into class I or class II. In order to classify the Zeltiq™ Dermal Cooling Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition FDA has determined that the Zeltiq™ Dermal Cooling Device indicated for use as a non-invasive dermatological aesthetic treatment to affect the appearance of flanks (love handles) 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.

In addition to the general controls of the Act, the Zeltiq™ Dermal Cooling Device is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use," to address the specific risks to health associated with this type device. The risks identified in the Special Controls Guidance Document: Contact Cooling System for Aesthetic Use are: discomfort, pain, tenderness, thermal injury, systemic response to cold, electrical shock, electromagnetic interference, inflammation/foreign body response, and use error.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the focused ultrasound device they intend to market and receive clearance, prior to marketing their device.

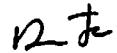
A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305),

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 this device as described in your petition.

If you have any questions concerning this classification order, please contact Mr. Richard P. Felten, General Surgery Devices Branch, at (301) 796-6392.

Sincerely yours,

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Abiy Desta
Acting Deputy Director for Science and
Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health