DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ulthera, Incorporated
% Randall E. Miller, Ph.D.
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JUN 3 2011

Re: K072505
Ulthera™ System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System for Aesthetic Use
Regulatory Classification: Class II
Product Code: OHV

Dear Dr. Miller:

This letter corrects our previous letter of September 11, 2009.

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 Ulthera™ System, a prescription device under 21 CFR Part 801.109 that is indicated for use as a non-invasive dermatological aesthetic treatment to lift the eyebrow to achieve a desired aesthetic effect. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Ulthera™ System, and substantially equivalent devices of this generic type, into class II.

FDA identifies this generic type of device as:

Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended 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 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 FD&C 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 FD&C 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 FD&C Act, FDA issued an order on March 14, 2008 automatically classifying the Ulthera™ 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 April 11, 2008, FDA filed your petition requesting classification of the Ulthera™ System into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Ulthera™ System 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 for its intended use.

After review of the information submitted in the petition FDA has determined that the Ulthera™ System indicated for use as a non-invasive dermatological aesthetic treatment to lift the eyebrow to achieve a desired aesthetic effect 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

Identified Potential Risk	**Recommended Mitigation Measure**
Thermal Injury from Focused Ultrasound Exposure (Thermal Damage)	Bench Testing Software Validation Animal Testing Clinical Testing Electromagnetic Compatibility Labeling
Mechanical Injury from Focused Ultrasound Exposure (Cavitation or other Mechanical Damage)	Bench Testing Software Validation Animal Testing Clinical Testing Labeling
Ocular Injury	Labeling
Electrical Shock	Electrical and Mechanical Safety Performance Testing Labeling
Inflammation/Foreign Body Response	Biocompatibility
Use Error	Labeling

In addition to the general controls of the FD&C Act, the Focused Ultrasound Stimulator System for Aesthetic Use is subject to the following special controls guidance document: *Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use*. 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 a premarket notification containing information on the Focused Ultrasound Stimulator System for Aesthetic Use 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 FD&C Act and the special controls identified in this order.

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

Sincerely yours,

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