

K122528 1/2

AUG 28 2012 08/17/2012

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## Attachment 5: 510(k) Summary

This 510(k) Summary for the Ulthera® System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

**Applicant:** Ulthera, Inc.

**Address:** 2150 South Country Club Drive, Suite 21  
Mesa, AZ 85210

**Contact Person:** Suzon Lommel, VP of Regulatory & Quality Affairs

**Telephone:** 480-649-4069

**Fax:** 480-619-4071

**Submission Date:** August 17, 2012

**Device Trade Name:** Ulthera® System

**Common Name:** Focused Ultrasound Stimulator Use System for Aesthetic Use

**Classification:** Regulatory Class II

**Classification Name:** Focused Ultrasound Stimulator Use System for Aesthetic Use

**Product Code:** OHV

**Legally Marketed Name:** Ulthera® System

**Predicates:** 510(k): #K072505

**Applicable Guidance:** The *Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use* was developed in response to Ulthera's DeNovo submission and 510(k) clearance K072505 for the Ulthera System.

**Device Description:** The Ulthera® System consists of the following components:

- Ulthera® Control Unit
- Handpiece
- Transducers



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- Indications for Use:** The Ulthera® System is indicated for use as a non-invasive dermatological aesthetic treatment to:
- lift the eyebrow
- Description of Change:** The proposed change is to extend the current six-month shelf life period to a twelve-month shelf life period for the Ulthera® System Transducers.
- Performance Data:** An accelerated aging study (per ASTM Standard F 1980 (2011)) was conducted to support the shelf life extension of the Ulthera® System Transducers from six months to one year. The results from the tests demonstrate that the technological characteristics and performance criteria of the subject device is comparable to the predicate device.
- Conclusion:** Based on the design, materials, principle of operation, and intended use, the Ulthera® System is substantially equivalent to the legally marketed predicate device. The Ulthera System Transducers met the predetermined acceptance criteria identified in the performance testing protocol. The results of the twelve-month shelf life study demonstrate that changing the current six-month shelf life period to a twelve-month shelf life period will have no detrimental effect on transducer functionality, patient safety or efficacy. Therefore, the predicate device is substantially equivalent to the subject device.





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  
% Ms. Suzon Lommel  
VP of Regulatory & Quality Affairs  
2150 South Country Club Drive, Suite 21  
Mesa, Arizona 85210

AUG 28 2012

Re: K122528  
Trade/Device Name: Ulthera<sup>®</sup> System  
Regulation Number: 21 CFR 878.4590  
Regulation Name: Focused ultrasound stimulator system for aesthetic use  
Regulatory Class: Class II  
Product Code: OHV  
Dated: August 17, 2012  
Received: August 20, 2012

Dear Ms. Lommel:

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

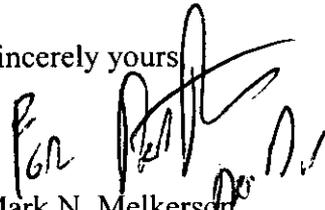
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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



Mark N. Melkers  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## Attachment 2: Indications for Use Statement

510(k) Number: Unknown K122528

Device Name: Ulthera® System

**Indications for Use:**

The Ulthera® System is indicated for use as a non-invasive dermatological aesthetic treatment to:

- lift the eyebrow

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Onda for MKN  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K122528

