DEC 11 2013

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:	1840 South Stapley Drive Suite 200 Mesa, AZ 85204
Contact Person:	Suzon Lommel, VP of Regulatory & Quality Affairs
Telephone:	480-619-4069
Fax:	480-619-4071
Submission Date:	June 28, 2013
Device Trade Name:	Ulthera® System
Common Name:	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption System, Imaging, Pulsed Echo, Ultrasonic
Classification:	Regulatory Class II
Classification Name:	Focused Ultrasound Stimulator Use System for Aesthetic Use
Regulation:	878.4590
Product Code:	OHV IYO
Legally Marketed	Name: Ulthera® System
Predicates:	510(k): Ulthera, Inc., Ulthera System - K121700 Cortex Technology, DermaScan C - K983945
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.

Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

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

- Ulthera® Control Unit
- Handpiece
- Transducers

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

- lift the eyebrow (current cleared indication)
- lift lax submental (beneath the chin) and neck tissue (cleared indication)

The Ulthera System in conjunction with the Ulthera DeepSEE transducer allows for ultrasonic visualization of depths up to 8 mm below the surface of the skin. The indicated use of the imaging is to visualize the dermal and subdermal layers of tissue to:

- ensure proper coupling of the transducer to the skin (requested indication)
- confirm appropriate depth of treatment such as to avoid bone (requested indication)

Performance Data: No new performance testing was performed to support the new indications. There have been no changes to previously cleared device (K121700, Ulthera® System) that would result in a new 510(k). Imaging capabilities of the Ulthera® System have been included in the device's profile since the original clearance. Clinical literature and ultrasound images were provided.

Conclusion: There have been no changes to previously cleared Ulthera® System (K121700) that would result in a new 510(k).

The Ulthera System's imaging subsystem and the DermaScan C are equivalent in terms of patient contact material biocompatibility, electromagnetic compatibility, and medical electrical safety standards. The Ulthera System's imaging subsystem is equivalent in terms of general

specifications, device settings and intended use to the predicate device, DermaScan C (K983945).

Based on the design, materials, principle of operation, and intended use, the Ulthera® System is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ulthera Incorporated
Ms. Suzon Lommel
Vice President of Regulatory & Quality Affairs
1840 South Stapley Drive, Suite 200
Mesa, Arizona 85204

December 11, 2013

Re: K132028
Trade/Device Name: Ulthera® System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV, IYO
Dated: October 25, 2013
Received: October 28, 2013

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

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 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number: Unknown

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
- lift lax submental (beneath the chin) and neck tissue

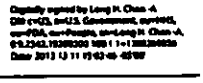
The Ulthera System in conjunction with the Ulthera DeepSEE transducer allows for ultrasonic visualization of depths up to 8 mm below the surface of the skin. The indicated use of the imaging is to visualize the dermal and subdermal layers of tissue to:

- ensure proper coupling of the transducer to the skin
- confirm appropriate depth of treatment such as to avoid bone

Prescription Use ___x___ **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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A  for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132028