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K134032

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:	Ashley Fickett, Regulatory Affairs Manager
Telephone:	(480) 619-4069
Fax:	(480) 214-0330
Submission Date:	February 19, 2014
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 Number:	878.4590
Product Code:	OHV IYO
Legally Marketed	Name: Ulthera® System
Predicate:	510(k): Ulthera, Inc., Ulthera System – K132028
Applicable Guidance:	The following guidance is applicable to the Ulthera System:

- 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.

- Conformance to *Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* was determined in the predicate 510(k) submission clearance K132028 for the Ulthera System.
- *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.*

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 (current cleared indication)
- improve lines and wrinkles of the décolleté (requested 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 (current cleared indication)
- confirm appropriate depth of treatment such as to avoid bone (current cleared indication)

Substantial Equivalence Comparison:

	Predicate Device : Ulthera® System (K132028)	Subject Device Ulthera® System; Expanded Indication for Use
Regulation	878.4590	878.4590 **Same**
Product Code	OHV, IYO	OHV, IYO **Same**
Intended Use/ Indications for Use	Non-invasive dermatological aesthetic treatment to: • lift the eyebrow (current cleared indication) • 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	Non-invasive dermatological aesthetic treatment to: • lift the eyebrow (current cleared indication) • lift lax submental (beneath the chin) and neck tissue • ***improve lines and wrinkles of the décolleté (requested 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 •confirm appropriate depth of treatment such as to avoid bone ***Clinical Performance Data Provided for Expanded Indication***
Where Used	Clinic/doctor's office	Clinic/doctor's office **Same**
Anatomical Site	Skin	Skin **Same**
Type of Energy	Thermal < 2 J	Thermal < 2 J **Same**
Biological Effect	Lifting of tissue via High Intensity Focused Ultrasound (HIFU) directed beneath the outer dermis in localized points at a specified depth and distance between points.	Reduction of lines and wrinkles via High Intensity Focused Ultrasound (HIFU) directed beneath the outer dermis in localized points at a specified depth and distance between points.

	Predicate Device : Ulthera® System (K132028)	Subject Device Ulthera® System; Expanded Indication for Use
		Same method of action
Demonstrated Safety and Efficacy in treated area	Provided in K072505 cleared September 11, 2009 Provided in K121700 cleared October 2, 2012 Provided in K132028 cleared December 11, 2013	Performance Testing - Clinical ***Clinical Performance Data Provided for Expanded Indication***
Patient Contact Material	Biocompatible	Biocompatible **Same**
Electromagnetic Compatibility Standards	Compliant	Compliant **Same**
Medical Electrical Equipment Safety Standards	Compliant	Compliant **Same**
Thermal Coagulation Point	Confined to focal zone; shallow (< 5 mm); no thermal coagulation below focal zone	Confined to focal zone; shallow (< 5 mm); no thermal coagulation below focal zone **Same**
Epidermal Impact	Non-invasive; no cooling required	Non-invasive; no cooling required **Same**
Pigmentation Effect	Chromophore insensitive	Chromophore insensitive **Same**
Packaging	Nylon / Aluminum foil laminate bag with very low water vapor transmission rate. The bag is enclosed within a cardboard box for storage.	Nylon / Aluminum foil laminate bag with very low water vapor transmission rate. The bag is enclosed within a cardboard box for storage. **Same**
Sterilization	Provided non-sterile	Provided non-sterile **Same**
Shelf Life	12 months	12 months **Same**

Performance Data:

Clinical analysis was conducted in clinical trials to support the clinical performance of the Ulthera® System. Sufficient safety data has been gathered to determine that the Ulthera® System performs as clinically intended.

To support the expanded indication, the Ulthera System was evaluated in a prospective safety and efficacy study investigating the clinical response following treatment with the Ulthera System to achieve improvement of lines and wrinkles of the décolleté. The clinical study's protocol was approved under IDE G120004 for enrolling up to 130 female subjects between the ages of 35-60 at up to 4 sites with a 90 and 180 day follow up. The Fabi-Bolton Scale, a published validated scale, was prospectively defined to evaluate wrinkle improvement. However, successful validation of the Fabi-Bolton Scale during the clinical trial could not be accomplished due to kappa scores for both intra-rater and inter-rater reproducibility being low. Therefore, the primary endpoint was changed from the Fabi-Bolton Scale to a post-hoc retrospective masked assessment of pre and post treatment photographs. There were no pre-specified success criteria of the masked assessment established at the beginning of the clinical trial. In addition to masked assessment, there was also an unmasked assessment called the Clinician Global Aesthetic Improvement Scores (CGAIS). Finally, patient satisfaction questionnaires were also measured to assess improvement.

Table 1. Patient Accountability

N	125
Subject Drop out	17
Subject Per Protocol	108
Subject Eliminated based on Poor Quality Photographs	54
Evaluable Subjects	54

Upon analysis of the all the photographs used in the clinical study, 54 of 108 day 180 photos were identified as having inconsistencies in photo quality (changes in lighting, color, focus, patient positioning, cropping, etc.). Therefore a sub-set analysis was conducted using the primary endpoint of masked assessment on the remaining 54 day 180 evaluable photo sets that were deemed the most consistent in photo quality.

Table 2 provides results from the masked assessment of the evaluable subject photos.

Table 2. Masked Assessment Results of Evaluable Subject Photos

N	54
Improvement	36 (~67%)
Incorrect	13 (24%)
No Change	5(9%)

In the sub-set of evaluable photos, there were 36 of 54 (~67%) subjects that showed improvement by masked assessment of pre and post treatment photographs at the primary endpoint of 180 days.

Table 3 provides CGAIS and Patient Assessments stratified by results of the primary endpoint of masked assessment for the subject sub-set with the most consistent photo quality.

Table 3. CGAIS and Patient Assessments Stratified By Masked Assessment Results for Sub-Set of Evaluation Photos

D180								
Masked Assessment	CGAIS			Patient Satisfaction			Patient Reported Improvement	
	Improved (improved, much improved, very much improved)	No Change	Worse	Satisfied (satisfied & very satisfied)	Neither Satisfied nor Dissatisfied	Dissatisfied (dissatisfied & very dissatisfied)	Yes	No
Improvement n=36	27 (75%)	9 (25%)	0 (0%)	23 (64%)	9 (25%)	4 (11%)	32 (89%)	4 (11%)
Incorrect n=13	5 (38%)	7 (54%)	1 (8%)	8 (61%)	4 (31%)	1 (8%)	10 (77%)	3 (23%)
No Change n=5	3 (60%)	2 (40%)	0 (0%)	4 (80%)	0 (0%)	1 (20%)	4 (80%)	1 (20%)
TOTAL – n = 54	35 (65%)	18 (33%)	1 (2%)	35 (65%)	13 (24%)	6 (11%)	46 (85%)	8 (15%)

The results of the sub-set analysis demonstrate improvement of lines and wrinkles based on masked assessment of pre and post treatment photographs in 36 of 54 evaluable subjects with the most consistent photo quality after one Ultherapy treatment 180 days post-treatment.

Please note that treatment efficacy was achieved at the pre-set energy levels of Level 4 for the 7 - 3.0 and 4 - 4.5 transducers and energy Level 3 for the 10 – 1.5 transducer. Changes in energy may impact efficacy.

Device safety was demonstrated as there were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the Ulthera System. Of the adverse events, all but two were mild. Only

two events were moderate, one of which was not device related. All events resolved.

Conclusion:

Based on the design, materials, principle of operation, and intended use, the subject device (Ulthera® System) is substantially equivalent to the legally marketed predicate device (Ulthera System, K132028) as demonstrated in the substantial equivalence comparison table. Clinical data determined that the subject device is as safe and effective and performs as well as the predicate device for the expanded indication.

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

June 20, 2014

Ulthera Incorporated
Ms. Ashley Fickett
Regulatory Affairs Manager
1840 South Stapley Drive, Suite 200
Mesa, Arizona 85204

Re: K134032
Trade/Device Name: Ulthera System
Regulation Number: 21 CFR 878.4590
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHV, IYO
Dated: December 30, 2013
Received: December 31, 2013

Dear Ms. Fickett:

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,

David Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K134032

Device Name
Ulthera® System

Indications for Use *(Describe)*
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
- improve lines and wrinkles of the décolleté

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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