



May 4, 2018

Ulthera, Inc
Mr. Steven J. Kachelmeyer
Executive Director, Regulatory Affairs
1840 South Stapley Drive Suite 200
Mesa, Arizona 85204

Re: K180623

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: March 7, 2018
Received: March 9, 2018

Dear Mr. Kachelmeyer:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jennifer R.
Stevenson -S3**

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

Indications for Use

510(k) Number (if known)

K180623

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; which can also affect the appearance of lax tissue in the submental and neck regions
- 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Applicant: Ulthera[®], Inc.
Address: 1840 South Stapley Drive, Suite 200
Mesa, AZ 85204
Contact: Steven J. Kachelmeyer - Executive Director, Regulatory Affairs
Telephone: (480) 619-4069
Fax: (480) 619-4071

Date Prepared: May 2, 2018
Device Trade Name: Ulthera[®] System
Common Name: Focused Ultrasound for Tissue Heat or Mechanical Cellular Disruption System, Imaging, Pulsed Echo, Ultrasonic
Classification Name: 21 C.F.R. § 878.4590, Focused Ultrasound Stimulator Use System for Aesthetic Use
Regulatory Class: Class II
Product Codes: OHV, IYO
Predicate Device: Ulthera[®], Inc. Ulthera[®] System (K134032)
Applicable Guidance: *Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.*

The device also conforms to *Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* and *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

Device Description: The Ulthera[®] System consists of the Ulthera[®] Control Unit (with system software), a handpiece with cable, and interchangeable transducers. The device produces controlled tissue coagulation below the skin surface (epidermis) within the first few millimeters of tissue (dermis) using highly focused, low-energy ultrasound deposition. The Ulthera[®] System directs micro-focused acoustic waves to the treatment area at desired depths without affecting or requiring a secondary action to protect the skin surface. The operator may also use the device's supplemental imaging capability to visualize the treatment area and aid in assuring full/proper skin contact of the Ulthera[®] System transducer to the skin in the target area.

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; which can also affect the appearance of lax tissue in the submental and neck regions
- 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

Summary of Technological Characteristics: High Intensity Focused Ultrasound (HIFU) is the underlying technological principle for both the subject and predicate devices. The Ulthera® System functions by directing ultrasonic energy beneath the outer dermis in localized points at a specified distance and depth between points. The design and performance characteristics of the subject and predicate devices are identical. The only technological differences between the devices are minor and do not raise different questions of safety or effectiveness for the subject device as compared to the predicate.

A table comparing the key features of the subject and predicate devices is provided below.

	Predicate Device: Ulthera® System (K134032)	Subject Device: Ulthera® System, Expanded Indications for Use
Regulation	21 C.F.R. § 878.4590	21 C.F.R. § 878.4590
Product Code	OHV, IYO	OHV, IYO
Intended Use/ Indications for Use	<p>Non-invasive dermatological aesthetic treatment to:</p> <ul style="list-style-type: none"> • lift the eyebrow • lift lax submental (beneath the chin) and neck tissue • improve lines and wrinkles of the décolleté <p>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:</p> <ul style="list-style-type: none"> • ensure proper coupling of the transducer to the skin • confirm appropriate depth of treatment such as to avoid bone 	<p>Non-invasive dermatological aesthetic treatment to:</p> <ul style="list-style-type: none"> • lift the eyebrow • lift lax submental (beneath the chin) and neck tissue which can also affect the appearance of lax tissue in the submental and neck regions • improve lines and wrinkles of the décolleté <p>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:</p> <ul style="list-style-type: none"> • ensure proper coupling of the transducer to the skin • confirm appropriate depth of treatment such as to avoid bone
Where Used	Clinic/doctor's office	Clinic/doctor's office
Anatomical Site	Skin	Skin
Type of Energy	Thermal, < 2 J	Thermal, < 2 J
Biological Effect	Lifting of tissue and 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	Lifting of tissue and 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
Patient Contact Material	Biocompatible	Biocompatible

Medical Electrical Equipment Safety and EMC	Compliant with relevant standards	Compliant with relevant standards
Thermal Coagulation Point	Shallow (< 5 mm) and confined – no thermal coagulation below focal zone.	Shallow (< 5 mm) and confined – no thermal coagulation below focal zone.
Epidermal Impact	Non-invasive; no cooling required	Non-invasive; no cooling required
Pigmentation Effect	Chromophore insensitive	Chromophore insensitive
System Software	Version 1382	Version 1700 – minor software updates to have GUI match cleared labeling in K134032, add improved security for transducer detection, and correct minor anomalies.
Device Labeling	Instructions for Use(IFU) and Technical Information Manual (TIM) shipped as two separate documents	Integrated Instructions for Use(IFU) and Technical Information Manual (TIM) into a single document to simplify translations. Added UDI labeling Updated symbols for IEC 60601-1-3.1 ed.
Packaging	Control Unit and Handpiece: Corrugated carton Transducer: Nylon / Aluminum foil laminate bag with very low water vapor transmission rate, enclosed within a	Control Unit and Handpiece: Corrugated carton Transducer: Nylon / Aluminum foil laminate bag with very low water vapor transmission rate, enclosed within a
Sterilization	Non-sterile	Non-sterile
Single-use/ Reusable	Controller and handpiece: Reusable Transducers: Single-use	Controller and handpiece: Reusable Transducers: Single-use
Shelf Life	12 months (transducer)	12 months (transducer)

Performance Data: To support the expanded indication, the Ulthera[®] System was evaluated in an open-label clinical trial investigating the clinical response following treatment with the Ulthera[®] System to achieve lifting of lax submental (beneath the chin) and neck tissue. Improvement was evaluated through quantitative assessment, qualitative assessment and patient satisfaction questionnaires. There were 51/70 patients that had an improvement of ≥ 20 mm² in lift, of these patients 84.3% were identified as showing improvement by masked evaluators. The adverse events resulting from treatment with the Ulthera[®] System during this study were mild, short-lived in duration, and resolved without incident. There were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the Ulthera[®] System.

Conclusion: The Ulthera[®] System is as safe and effective as the predicate Ulthera[®] System cleared by FDA in K134032. The subject device has the same intended use and very similar technological characteristics and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic use of the device, and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the subject Ulthera[®] System and its predicate raise no new types of safety or effectiveness questions. Thus, the Ulthera[®] System with modified indications for use is substantially equivalent to the legally marketed predicate device (K134032).