February 22, 2024

Ulthera, Inc.
Kim Kelly
Sr. Director, Regulatory Affairs
1840 S. Stapley Dr.
Suite 200
Mesa, Arizona 85204

Re: K233996
Trade/Device Name: Ulthera System (UC-1 Control Unit PRIME)
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System For Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: January 23, 2024
Received: January 23, 2024

Dear Kim Kelly:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.22 15:01:25 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233996

Device Name
Ulthera System (UC-1 Control Unit PRIME)

Indications for Use *(Describe)*
The Ulthera System is intended to apply focused ultrasound energy to the body to achieve temporary changes in the physical appearance of the skin.

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.

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"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

Company's Name:	Ulthera, Inc.
Company's Address:	1820 South Stapley Drive. Suite 200 Mesa, AZ 85204
Telephone:	(984) 286-9190
Contact Person:	Kim Kelly, Senior Director, Regulatory Affairs
Date Prepared:	February 22, 2024

DEVICE

Device Name:	Ulthera System (UC-1 Control Unit PRIME)
Classification Name:	Focused Ultrasound Stimulator System for Aesthetic Use
Classification Name:	21 C.F.R § 878.4590, Focused Ultrasound Stimulator Use
Regulatory Class:	Class II
Product Codes:	OHV, IYO
Applicable Guidances:	*Focused Ultrasound Stimulator System for Aesthetic Use* *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* *Content of Premarket Submissions for Software Contained in Medical Devices*.

PREDICATE DEVICE

Ulthera System, Ulthera, Inc., K180623

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.

INTENDED USE / INDICATIONS FOR USE

The Ulthera System is intended to apply focused ultrasound energy to the body to achieve temporary changes in the physical appearance of the skin.

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

The purpose of this 510(k) notification relates to modifications to the console of the Ulthera System. Low-intensity, highly focused ultrasound is the main technological principle of both the subject and the predicate device. In both devices, focused ultrasound energy is delivered below the skin and produces discrete points of thermal coagulation that results in contraction of the skin, which produces a lifting or tightening effect and improves appearance of lax tissue, lines, and wrinkles. Both the subject and predicate device share the following similar technological elements:

- Identical ultrasound signal energy and ultrasound treatment guidelines

- Same main components, including a console with integrated touchscreen, connected handpiece, and interchangeable transducers

- An imaging mode of operation to visualize the treatment area and aid in assuring full/proper skin contact of the transducer to the skin

The following differences between the subject and predicate device do not significantly affect clinical functionality or performance specifications of the device and have been verified and tested:

- Updates to the console's industrial design and modernization of the graphics within the graphical user interface (GUI)

- Hardware updates to comply with the latest electromedical standards and address end-of-life components

Comparison between the subject and predicate device are summarized in Table 1 below:

Table 1: Substantial Equivalence Table Comparing Subject & Predicate Devices

	Ulthera Modified Console Subject Device	**Ulthera Console K180623 (Predicate)**
Intended Use	The Ulthera System is intended to apply focused ultrasound energy to the body to achieve temporary changes in the physical appearance of the skin.	The Ulthera System is intended to apply focused ultrasound energy to the body to achieve temporary changes in the physical appearance of the skin.
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	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

User Population	Treatment of adult patient population by trained medical professional	Treatment of adult patient population by trained medical professional
Main System Components	• Control console • Handpiece • Transducers	• Control console • Handpiece • Transducers
Additional Components Required for Operation	• ACLF Power Cord with pigtail adapter • USB Access Key	• Power cord • USB Access Key
Dimensions (l x w x h)	Height: <16.69" (424 mm) Width: 19.4" (493.6 mm) Depth: 13.1" (333 mm)	Height: 15.3" (389 mm) Width: 16.5" (419 mm) Depth: 13.0" (330 mm)
Weight	Weight: ≤27 lbs (12.2 kg)	Weight: 22 lbs (10 kg)
Display	18.5” screen; aspect ratio of 16:9 with 1920 x 1080 resolution	15” screen; aspect ratio of 4:3 with 1024 x 768 resolution
Power Source	100-240 VAC, 50/60 Hz, 3A max Fuse: (2) 5x20mm, 6.3A fast acting, 250V	100-240 VAC, 50/60 Hz, 3A max Fuse: (2) 5x20mm, 6.3A fast acting, 250V
Biocompatibility	Biocompatible user contacting surfaces	Biocompatible user contacting surfaces
Software	version 2.1.2030	version 1700
Operating System	Windows 10	Windows XP
Electrical Safety & EMC standards	Compliant with relevant IEC standards for console and ACLF power cord	Compliant with relevant IEC standards for console

PERFORMANCE DATA

The following non-clinical data were provided to support the substantial equivalence of the subject device to the predicate device. In all instances, the subject device functioned as intended.

Biocompatibility

Biocompatibility of the user-contacting components of the device was verified in accordance with ISO 10993-1.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC of the subject device were verified in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-37, and IEC 60601-2-62.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA Guidance, "Content of Premarket Submissions Device Software Functions." A basic documentation level was used, as a failure or flaw of any device software function(s) would not present a hazardous situation with a probable risk of death or serious injury prior to the implementation of risk control measures.

Usability

Usability testing was conducted in accordance with IEC 62366-1 and FDA Guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*." The console's portability, GUI visibility and layout, and display responsiveness were also verified. Testing demonstrated that clinicians were able to use the device in a representative environment and use conditions. No new risks were identified during the stimulated use study.

Mechanical Testing

The display hinge of the console was verified via mechanical cyclic testing.

Packaging, Transit, and Environmental Testing

Packaging and transit testing were conducted per ASTM D4169 and ASTM D4332. Environmental conditioning testing was conducted to verify device functionality at defined operating and storage conditions.

Ultrasound Output Testing

Acoustic reliability was verified using simulated treatment over the device's service life. Power output and imaging were verified to be within specification.

CONCLUSIONS

The modified console has undergone robust performance testing, including software, mechanical, electrical safety, electromagnetic compatibility, packaging, environmental, and usability testing. Imaging and acoustical testing were also conducted to verify the ultrasound signal. These non-clinical performance tests of the Ulthera System demonstrated the modified console continues to operate as intended and that it is as safe and effective as its predicate for the proposed indications for use.