May 13, 2025

Ulthera Inc.
Christopher Lefancheck
Senior Regulatory Affairs Specialist
6501 Six Forks Road
Raleigh, North Carolina 27615

Re: K250418
Trade/Device Name: Ulthera System (UC-1 Control Unit PRIME Model 2.1)
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV, IYO
Dated: February 13, 2025
Received: February 13, 2025

Dear Christopher Lefancheck:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.05.13 17:34:42 -04'00'

James Jang, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250418

Device Name
Ulthera System (UC-1 Control Unit PRIME Model 2.1)

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.
• improve the appearance of skin laxity on the abdomen, anterior arms, and posterior arms.

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
PRAStaff@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

1 APPLICANT

Company's Name: Ulthera, Inc.

Company's Address: 6501 Six Forks Road
Raleigh, NC 27615

Telephone: 919.215.4879

Contact Person: Christopher Lefancheck, Sr. Regulatory Affairs Specialist

Date Prepared: May 9th, 2025

2 DEVICE

Device Name: Ulthera System (UC-1 Control Unit PRIME Model 2.1)

Classification Name: Focused Ultrasound Stimulator System for Aesthetic Use
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.

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

3 PREDICATE DEVICE

Ulthera System (UC-1 Control Unit PRIME), Ulthera, Inc., K233996

Ulthera System (UC-1 Control Unit PRIME), Ulthera, Inc., K243035

4 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.

5 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
- Improve the appearance of skin laxity on the abdomen, anterior arms, and posterior arms

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

6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this 510(k) notification relates to changes to the software of the Ulthera System to allow for wireless connectivity and implement the new treatment planning mode SEE.PLAN.TREAT.®. 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.
- 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 minor software and hardware differences between the subject and predicate systems (see Table 1) do not affect clinical functionality or performance specifications of the system and have been verified and tested.

Table 1: Substantial Equivalence Table Comparing Subject & Predicate Device

	Ulthera System (Subject Device)	**Ulthera System K233996 (Predicate)**	**Ulthera System K243035 (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.	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 • Improve the appearance of skin laxity on the abdomen, anterior arms, and posterior arms	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	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 • Improve the appearance of skin laxity on the abdomen, anterior arms, and posterior arms

	Ulthera System (Subject Device)	**Ulthera System K233996 (Predicate)**	**Ulthera System K243035 (Predicate)**
	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	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 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	Treatment of adult patient population by trained medical professional
Main System Components	• Control console • Handpiece • Transducers	• Control console • Handpiece • Transducers	• Control console • Handpiece • Transducers
Additional Components Required for Operation	• ACLF Power Cord with pigtail adapter • Wibu USB Access Key	• ACLF Power Cord with pigtail adapter • CrypKey USB Access Key	• ACLF Power Cord with pigtail adapter • CrypKey USB Access Key
Console Dimensions	Height: <16.69" (424 mm) Width: 19.4" (493.6 mm) Depth: 13.1" (333 mm)	Height: <16.69" (424 mm) Width: 19.4" (493.6 mm) Depth: 13.1" (333 mm)	Height: <16.69" (424 mm) Width: 19.4" (493.6 mm) Depth: 13.1" (333 mm)
Console connection ports	6	2	2
Weight	Weight: ≤27 lbs (12.2 kg)	Weight: ≤27 lbs (12.2 kg)	Weight: ≤27 lbs (12.2 kg)
Display	18.5” screen; aspect ratio of 16:9 with 1920 x 1080 resolution	18.5” screen; aspect ratio of 16:9 with 1920 x 1080 resolution	18.5” screen; aspect ratio of 16:9 with 1920 x 1080 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	100-240 VAC, 50/60 Hz, 3A max Fuse: (2) 5x20mm, 6.3A fast acting, 250V
Software	version 2.1.6400	version 2.1.2030	version 2.1.2036
Treatment Modes	Amplify SEE.PLAN.TREAT.®	Amplify	Amplify
Ultrasound Color Maps	Black & White (monochromatic) Bone (blue scale) Twilight (multicolor)	Black & White (monochromatic)	Black & White (monochromatic)
Wireless Connectivity	Connection via USB Wi-Fi Adapter	None	None
Operating System	Windows 10	Windows 10	Windows 10

	Ulthera System (Subject Device)	Ulthera System K233996 (Predicate)	Ulthera System K243035 (Predicate)
Electrical Safety & EMC standards	Compliant with relevant IEC standards for console and ACLF power cord	Compliant with relevant IEC standards for console and ACLF power cord	Compliant with relevant IEC standards for console and ACLF power cord

7 PERFORMANCE DATA

The following nonclinical 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.

7.1 Electrical Safety

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

7.2 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.

7.3 Usability

Usability testing was conducted in accordance with IEC 62366-1 and FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices." Testing was focused upon useability of the new SEE.PLAN.TREAT.® mode of the system. 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.

7.4 Cybersecurity

Cybersecurity testing was conducted, and documentation was provided as recommended by FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

8 CONCLUSIONS

The subject device has the same general intended use and principle of operation as the predicate device. The minor changes in device hardware and software do not raise different questions of

safety or effectiveness and do not affect clinical functionality or performance specifications. These changes have been verified and validated through nonclinical performance testing, including biocompatibility, software verification and validation, cybersecurity testing, and electrical safety.

In summary, the nonclinical performance testing has demonstrated that the subject device operates as intended and that it is as safe and effective as the predicate for the proposed indications for use.