May 21, 2026

Ulthera, Inc.
Scott Jewett
Regulatory Affairs Manager
6501 Six Forks Rd.
Raleigh, North Carolina 27560

Re: K260618
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: February 25, 2026
Received: February 25, 2026

Dear Scott Jewett:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.21 21:49:12 -04'00'

Colin K. Chen, 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)*
K260618

Device Name
Ulthera® System

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, posterior arms, and knees

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.

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: Scott Jewett, Regulatory Affairs Manager

Date Prepared: 12 May 2026

2 DEVICE

Device Name: Ulthera® System

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

3 PREDICATE DEVICE

Ulthera® System (UC-1 Control Unit PRIME), Ulthera, Inc., K250418

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, posterior arms, and knees

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 expanded indications for the Ulthera® System to improve the appearance of skin laxity on the knees. 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. There are no changes in design, hardware, or software between subject and predicate device. Comparison between the subject and predicate device are summarized in Table 1 below:

Table 1: Substantial Equivalence Table Comparing Subject & Predicate Device

	Ulthera® System (Subject)	Ulthera® System K250418 (Predicate)	Similarities and significant differences to the 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.	Identical
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, posterior arms, *and knees* 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. • 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	Different Additional indications added for the knees. Clinical data, real-world evidence (RWE), and post market surveillance (PMS) data have been provided to demonstrate the safety and effectiveness of the device for the expanded indications and support the expansion of the subject device's indications for use.
User Population	Treatment of adult patient population by trained medical professional	Treatment of adult patient population by trained medical professional	Identical
Main System Components	• Control console • Handpiece • Transducers	• Control console • Handpiece • Transducers	Identical
Additional Components Required for Operation	• ACLF Power Cord with pigtail adapter • Wibu USB Access Key	• ACLF Power Cord with pigtail adapter • Wibu USB Access Key	Identical
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)	Identical

	Ulthera® System (Subject)	Ulthera® System K250418 (Predicate)	Similarities and significant differences to the predicate
Console Connection Ports	6	6	Identical
Weight	Weight: ≤27 lbs (12.2 kg)	Weight: ≤27 lbs (12.2 kg)	Identical
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	Identical
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	Identical
Software	version 2.1.6400	version 2.1.6400	Identical
Treatment Modes	Amplify See.Plan.Treat	Amplify See.Plan.Treat	Identical
Ultrasound Color Maps	Black & White (monochromatic) Bone (blue scale) Twilight (multicolor)	Black & White (monochromatic) Bone (blue scale) Twilight (multicolor)	Identical
Wireless Connectivity	Connection via USB Wi-Fi Adapter	Connection via USB Wi-Fi Adapter	Identical
Operating System	Windows 10	Windows 10	Identical
Electrical Safety & EMC	Compliant with relevant IEC standards for console and ACLF power cord	Compliant with relevant IEC standards for console and ACLF power cord	Identical

7 PERFORMANCE DATA

7.1 Clinical Testing

To support the device's indications for use, a comprehensive literature search was performed, and three (3) unique clinical studies were identified that used the Ulthera® System to improve the appearance of skin laxity on the knees. These studies included 44 total subjects, which is comparable to and/or exceeds the number of subjects evaluated in the previous 510(k) clearances for the Ulthera® System and other focused ultrasound stimulator systems for aesthetic use.

These clinical studies demonstrated clinically significant skin improvement up to 180 days post-treatment via a variety of endpoints, including blinded clinician photographic assessment, physician and subject Global Aesthetic Improvement Scores (GAIS), and patient satisfaction surveys. From a safety perspective, there were no unexpected or severe adverse events (AEs), and all observed AEs resolved without long-term sequalae.

Additionally, the Company also obtained real-world data (RWD) gathered from clinicians who regularly treat the knee region with the Ulthera® System. No unexpected adverse events were reported, including no reports of joint, muscle, or tendon damage.

Lastly, there has not been any orthopedic-based adverse events of the knee reported from global post marketing surveillance of the device. Collectively, the totality of evidence supports the safety of the Ulthera® System for treating the knees.

8 CONCLUSIONS

The subject device has the same general intended use and principle of operation as the predicate device, and there have been no changes in device hardware, software, or firmware compared to the predicate device. An analysis of clinical, real-world, and post marketing data demonstrates that the device is as safe and effective as the predicate device for the requested indications for use.