October 9, 2019

Ulthera, Inc
Lisa Pray
Regulatory Affairs Manager
1840 S. Stapley Dr. Suite 200
Mesa, Arizona 85204

Re: K192185
Trade/Device Name: The Cellfina System
Regulation Number: 21 CFR 878.4790
Regulation Name: Powered Surgical Instrument for Improvement in the Appearance of Cellulite
Regulatory Class: Class II
Product Code: OUP
Dated: August 9, 2019
Received: August 12, 2019

Dear Lisa Pray:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Long Chen, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192185

Device Name
Cellfina System

Indications for Use *(Describe)*
The Cellfina System is intended for long term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits through five years of observation.

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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510(k) Summary

This 510(k) Summary for the Cellfina 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.

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Contact Person: Lisa Pray, Regulatory Affairs Manager

Telephone: (480) 828-8856

Fax: (480) 619-4071

Submission Date: August 9, 2019

Device Trade Name: The Cellfina System

Common Name: Powered surgical instrument for improvement in the appearance of cellulite.

Classification: Regulatory Class II

Classification Name: Powered surgical instrument for improvement in the appearance of cellulite.

Regulation Number: 21CFR 878.4790

Product Code: OUP

Legally Marketed Predicate: The Cellfina System, 510(k): K161885

Applicable Guidance: The following guidance special controls are applicable to the Cellfina System:

Class II (special controls). The special controls for this device are:

(1) Non-clinical testing must be performed to demonstrate that the device meets all design specifications and performance requirements, and to demonstrate durability and mechanical integrity of the device.
(2) In vivo evaluation of the device must demonstrate device performance, including the safety of the release methodology and blood loss at the treatment sites.
(3) All elements of the device that may contact the patient must be demonstrated to be biocompatible.
(4) Electrical safety and electromagnetic compatibility of the device must be demonstrated.

(5) The labeling must include a summary of in vivo evaluation data and all the device specific warnings, precautions, and/or contraindications.
(6) Sterility and shelf-life testing for the device must demonstrate the sterility of patient contacting components and the shelf life of these components.

Device Description: The Cellfina System is intended to provide precise focal release of subcutaneous tissue for improvement in the appearance of cellulite. The system consists of a sterile, single-use, disposable kit (CK1) and an electromechanical, non-sterile, 50-use motor module (CM1).

Indications for Use: The Cellfina System is intended for long term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits through five years of observation.

Substantial Equivalence Comparison:

The subject device remains unchanged from the predicate device. There has been no design, material, shelf life, cleaning and disinfection, software, or packaging updates since the predicate 510(k) submission (K161885). The subject device instructions for use have been updated to reflect compliance to IEC 60601-1-2 and to include the expanded indications for use statement.

Non-clinical Performance Data:

There have been no device changes to the subject device since the predicate device 510(k) K161885 submission. As such, all non-clinical performance data presented within the predicate device submission remains applicable to the subject device.

The only non-clinical performance data included in this submission is updated electromechanical safety testing. The predicate device of this Traditional 510(k) submission was compliant to IEC 60601-1-2:2007 3rd Edition; however, the subject device is now compliant to IEC 60601-1-2:2014 4th Edition.

Clinical Performance Data (In-Vivo):

The safety and effectiveness of the Cellfina System was evaluated in a pivotal clinical study conducted under IDE G120116. No additional treatments were performed at any follow-up time points. The overall study success was met (as defined within the protocol), despite the reduction in follow up participation at 5 years with a clinically significant, long term improvement in the appearance of cellulite in the treated subjects as shown within Table 05-1.

Table 05-1: Clinical Study Design Characteristics

Study Design:	Prospective, multi-center, non-randomized open label, safety and effectiveness study
Sample Size	55 Subjects participated in the baseline assessment and treatment
Follow up (N)	3 Day (55), 14 Day (54), 1 Month(54), 3Month (55), 6 Month (52), 1 year (50), 2 year (52), 3 year (45), 5 year (37)
Inclusion Criteria	Female between the ages of 18 and 55, BMI less than 35
Exclusion Criteria	No prior drug treatment for contouring or cellulite during prior 90 days; no prior liposuction of thighs or buttocks, subject has had >10 % weight loss in prior 6 months; subject has known difficulty with local anesthesia, subject is pregnant, other minor criteria
Primary Endpoint result at 5 years	The primary endpoint was met: achievement of ≥1 point average reduction in the 0-5 point Cellulite Severity Scale as determined by independent physician assessment of subject photographs taken before and (5 years) after treatment. • The mean improvement was 1.8 points ($p<0.0001$) with a 97.5% upper confidence limit improvement of 1.4 points.
Secondary Efficacy result at 5 years	The powered secondary endpoint was met: improvement of one grade or more in severity (none, mild, moderate, severe) in >60% of treated subjects as determined by independent physician assessment of subject photographs taken before and 5 years after treatment. • 86.5% of treated subjects had ≥1-grade improvement with a 95% lower confidence limit of 74.7%.
Primary Safety Result	The safety endpoint was met: 100% of subjects were free from Serious Adverse Events (SAE) directly attributable to the Cellfina System or procedure at 5 years
Additional Measures	All additional secondary measures were also achieved or acceptable at the 5 year time point: • The mean overall rate of correct selection was 92.8% with a lower 95% confidence limit of 86.3%. • 100% of the subjects had noticeable improvement by the GAIS and 35% were characterized as having Much Improved or Very Much Improved • 78% of the subjects were either Satisfied or Very Satisfied. • No subjects reported pain in the treatment area using an 11-point numerical rating scale at the 5-year follow-up visit.

Conclusion:

This Traditional 510(k) Premarket Notification is for an expanded indication for use statement. The included clinical data demonstrates that the Cellfina System is both safe and effective for the long term improvement in the appearance of cellulite in the buttocks

and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits through five years of observation.

No design modifications to the Cellfina System motor module (CM1) or disposable kit (CK1) have occurred since the predicate device submission, 510(k) K161885. Updated labeling has been provided as part of this 510(k) submission for updated compliance to IEC 60601-1-2:2014.

These updated indications for use and labeling do not pose any new questions of safety, product output or efficacy. The subject device Cellfina System is as safe, as effective, and performs as well as the legally marketed predicate device (K161885), and as such, is substantially equivalent.