DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 5, 2016

Ulthera, Inc.
Ms. Suzon Lommel
Vice President, Regulatory & Quality Affairs
1840 S Stapley Drive, Suite 200
Mesa, Arizona 85204

Re: K161885
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: July 8, 2016
Received: July 11, 2016

Dear Ms. Lommel:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K161885

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 up to 3 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.

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."

5. 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.

Address: 1840 South Stapley Drive
Suite 200
Mesa, AZ 85204

Contact Person: Kristen DeJeu, Regulatory Affairs Specialist

Telephone: (408) 822-6507

Fax: (480) 619-4071

Submission Date: July 08, 2016

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): K153677

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 up to 3 year of observation.

Substantial Equivalence Comparison:

The subject device and the predicate device are similar in the following ways: same regulation number and product code, anatomical use area, clinical use group (doctor's office, clinic), energy type with the same mechanism of action, packaging materials and configuration are unchanged, there are no differences in patient contacting materials, design of the CK1 Disposable Kit is the same, and the sterilization SAL is the same (EO, SAL 10^{-6}). Both devices are compliant to IEC 60601 standards and EMC standards.

The subject device differs from the predicate device in that the subject device is intended for 3 year efficacy whereas the predicate is intended for 2 year efficacy. In addition, the subject device's CK1 Disposable Kit has a shelf life of 24 months, whereas the predicate device had a shelf life of 12 months. The subject device CK1 is now qualified for a fully validated sterilization cycle, whereas the predicate went through a sterilization batch release process. The Subject Motor Module is intended for use up to 50 uses, whereas the predicate was intended for use up to 15 uses. The subject Motor Module is now validated for two types of cleaning methods (IPA based wipes and Chloride based wipes). The housing material for the enclosure and power button also changed from ABS and Elastomer to Makroblend and Wacker Elastosil, respectively in order to include a more robust material type that would withstand the new cleaning method. These are non-patient contacting materials and therefore additional biocompatibility testing was not necessary. The predicate device was only validated for one type of cleaning (Chloride based wipes). The subject device Motor Module includes minor tolerance changes to allow for injection molding, whereas the predicate was machined. Minor changes to location of epoxy, simplification of design to remove metal pin and using screws instead of heat staking were made to accommodate a 50 use "use life". The subject device will have a separate IFU for the CK1 and CM1, whereas the predicate utilized identical IFUs with repetitive information.

Non-clinical Performance Data:

Bench testing was performed to verify that the modifications to the subject device do not impact the safety or effectiveness of the device. Retesting for EMC and IEC 60601 was completed for the motor module to ensure that the changes in design would have no impact on safety or efficacy. Shelf life testing and use life testing were conducted on the CK1 and CM1 respectively for the changes in shelf and use life, which demonstrated full functionality. Cleaning and disinfection testing was conducted for the addition of the cleaning method for the motor module

with no impact to device performance. Sterilization validation was completed for the CK1 disposable kit in order to remove the requirement for batch release testing. The SAL level and sterilization method (EO) remains the same.

Clinical Performance Data (In-Vivo):

The safety and effectiveness of the Cellfina System was evaluated in a pivotal clinical study conducted under IDE G120116. The IDE was modified to allow for extended follow-up clinical performance data to be gathered for safety and efficacy at 3 years. No additional treatments were performed.

During the course of the 3 year Clinical study, 10 of the 55 subjects were lost to follow up. The reason for loss to follow up ranged from inability to contact the subject after multiple attempts to the subject removing herself from the study. Imputation analyses were performed for the 10 missing subjects from the 3 year report and carried out using the last observation carried forward (LOCF) for both the primary and 1st secondary endpoints using a paired t-test as well as multiple imputation for the primary effectiveness endpoint only, which met the study endpoint. The overall study success was met, despite the reduction in follow up participation at 3 years with a clinically significant, long term improvement in the appearance of cellulite in the treated subjects. The table below is based on the LOCF data and accounts for the 10 missing subjects:

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)
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 3 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 (3 years) after treatment. • The average improvement was 2.0 points ($p<0.0001$) with the 97.5% confidence limit of a 1.7 point improvement
Secondary Efficacy result at 3 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 3 years after treatment. ▪ 91.1% of treated subjects had improvement of 1 grade with a 95% confidence limit of 81.6%.
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 3 years
Additional	All additional secondary measures were also achieved or acceptable at the 3

Measures	year time point: • The average rate of correct selection was 97% with a 95% confidence limit of 92.6%. • 100% of the subjects had noticeable improvement by the GAIS and 56% were characterized as having marked improvement or better. • 93% of the subjects were either satisfied or very satisfied as evaluated by a 5 point Likert type scale at the 3 year follow-up. • 71% of subjects rated pain ≤ 3/10 at 3 days, and over 95% rated pain ≤ 3/10 thereafter. There were no subjects who reported pain at the 3 year follow-up.

Conclusion:

This Traditional 510(k) Premarket Notification is for an expansion to the indications for use (from 2 years to 3 years). Additionally, the motor module (CM1) use life has been extended from 15 uses to 50 uses and the shelf life of the disposable kit (CK1) has been extended from a 12 month shelf life to a 24 month shelf life. Labeling changes have also been implemented to reflect the above described changes. Additional testing was performed for compliance to Amendment 1:2012 (Edition 3.1) of 60601-1 and EMC 60601-1-2:2007 3rd Edition.

These changes do not pose any new questions of safety, product output or efficacy. As demonstrated through bench testing and clinical data, the subject device Cellfina System is as safe, as effective, and performs as well as the legally marketed predicate device (K153677), and as such, is substantially equivalent.