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

Ulthera Incorporated
Ms. Suzon Lommel
Vice President Regulatory and Quality Affairs
1840 South Stapley Drive, Suite 200
Mesa, Arizona 85204

July 29, 2015

Re: K150505
Trade/Device Name: 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: June 24, 2015
Received: June 30, 2015

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" (21CFR 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 yours,

Joshua C. Nipper -S

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)*
K150505

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 2 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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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:	Suzon Lommel, Vice President Regulatory and Quality Affairs
Telephone:	(408) 645-4979
Fax:	(480) 619-4071
Submission Date:	February 20, 2015
Device Trade Name:	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:	Cellfina System (trade name previously Cabochon System), 510(k): K134010
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 release of subcutaneous tissue for improvement in the appearance of cellulite is a minimally invasive surgical technique by physicians using a variety of manual surgical instruments and accessories. The Cellfina device consists of a powered cutting blade and a means for instrument guidance to control the depth, size and shape of the area of the tissue release. The system consists of a sterile single use disposable kit and a non-sterile reusable motor module.

Substantial Equivalence Comparison:

	Predicate Device **K134010, Cellfina System**	**Subject Device** **Cellfina System**
Intended Use/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 1 year of observation.	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 2 years of observation. *Clinical performance data provided for expanded indication*
Where used	Clinic/Doctor's Office	Clinic/Doctor's Office

		Same
Anatomical Site	Buttocks and thighs	Buttocks and thighs **Same**
Type of Energy	Mechanical movement driven by wall powered motor module	Mechanical movement driven by wall powered motor module **Same**
Biological Effect	Controlled mechanical cutting of the fibrous tissue (septae) which contributes to the appearance of cellulite. The Cellfina System controls and stabilizes the cutting motion used by physicians with the needle based release procedure.	Controlled mechanical cutting of the fibrous tissue (septae) which contributes to the appearance of cellulite. The Cellfina System controls and stabilizes the cutting motion used by physicians with the needle based release procedure. **Same**
Location of Motor Module Label	Attached to the DC power cable	Adheres to the bottom of the motor module *No change to content*
Sterilization	Disposable Kit, CK1: Ethylene Oxide, SAL 10^{-6}	Disposable Kit, CK1: Ethylene Oxide, SAL 10^{-6} **Same**
	Motor Module, CM1: Sterile dome provided; use with disinfecting wipes	Motor Module, CM1: Sterile dome provided; use with disinfecting wipes **Same**
Shelf Life	Disposable Kit, CK1: 6 months	Disposable Kit, CK1: 6 months **Same**
	Motor Module, CM1: Undefined uses	Motor Module, CM1: 15 uses *Cleaning and Disinfection Data provided*
Packaging	Disposable Kit, CK1: • 3 Tyvek pouches	Disposable Kit, CK1: • 1 Thermoformed tray with Tyvek sealed outer tray

	• Inner shipping chipboard box • Outer corrugated shipper box Motor Module, CM1: Packaged with disposable kit	• Foam insert within outer corrugated shipper box • Outer corrugated shipper box o Larger size to accommodate tray Motor Module, CM1: individually packaged *Packaging Testing Provided*
Biocompatibility	Biocompatible	Biocompatible *Biocompatibility Testing Provided*
Electromagnetic Compatibility Standards	Compatible	Compatible **Same**
Medical Electrical Equipment Safety Standards	Compatible	Compatible *Medical Electrical Equipment Safety Testing Provided*
Motor Module (CM1) Design Modifications	Motor Controller; Mechanical fuse in secondary box (motor controller) 3 piece enclosure design Machined	Motor Controller; Firmware fuse integrated into motor module 2 piece enclosure design Machined *Functional Testing Provided*
Disposable Kit (CK1) Design Modifications	Machined Internal adhesive, Loctite 3321 1 PTFE cover (tube) for both the anesthesia needle and the blade	Molded; minor dimensional changes to bottom plate to mate with CM1 due to transition from machined to molded. Internal adhesive, Loctite 4311 2 individual PTFE covers (tubes); one for the anesthesia needle and 1 for blade *Functional Testing Provided*

Demonstrated Safety and Efficacy in treated area	Clinical performance data provided for safety and efficacy at 3 months under IDE G120116 – De Novo K101231, cleared July 12, 2013 Clinical performance data provided for safety and efficacy at 1 year under IDE G120116 – 510(k) K134010, cleared April 14, 2014	Extended follow-up clinical performance data provided for safety and efficacy at 2 years under IDE G120116 *Clinical Follow-up Data Provided*

Bench Performance Data:

Comprehensive bench testing has been successfully completed for the Cellfina System on aged product. Testing was performed on finished, sterile, aged devices that were exposed to environmental and transportation conditioning prior to testing which included simulated use, durability, and mechanical integrity. All devices were shown to meet the predetermined acceptance criteria.

Clinical Performance Data:

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 2 years. No additional treatments were performed.

A prospective, multi-center, non-randomized open label, safety and effectiveness study was conducted for improvement of the appearance of cellulite. All subjects served as their own control and underwent a single treatment with the Cellfina System. Subjects underwent follow-up assessments at 3 days, 14 days, 1 year and 2 years post treatment. The subjects were asked to rate their satisfaction with their appearance and pain. Photographs were taken in accordance with a protocol-specific procedure at baseline and each follow-up. An independent and blinded reviewer of the photographs before treatment and at 2 years was used to verify the effectiveness of the procedure. A DSMB was formed and independently managed to provide safety oversight for the study.

All endpoints were achieved. The primary safety endpoint, defined as freedom from serious adverse events attributable to the procedure or device was achieved for all subjects (100%). The overall study success criteria was met with a clinically significant, long term improvement in the appearance of cellulite in the treated subjects defined by the following:

- 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 2 years after treatment.
    - The average improvement was 2.0 points ($p<0.0001$) with the 97.5% confidence limit of a 1.8 point improvement.

- 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 2 years after treatment.
    - 88.5% of treated subjects had improvement of 1 grade with a 95% confidence limit of 79.2%.
- The safety endpoint was met: 100% of subjects were free from Serious Adverse Events (SAE) directly attributable to the Cellfina™ System or procedure.

All additional secondary measures were also achieved or acceptable at the 2 year timepoint:

- The average rate of correct selection by independent physician assessment of blinded subject photographs taken before and was 98.1% with a 95% confidence limit of 94.5%.
- 100% of the subjects had noticeable improvement by the GAIS and 52% were characterized as having marked improvement or better by independent physician assessment of blinded subject photographs taken before and 2 years after treatment.
- 96% of the subjects were either satisfied or very satisfied as evaluated by a 5 point Likert type scale at the 2 year follow-up.
    - Subject reported pain on a 0-10 numerical rating scale was 4.5 for the delivery of anesthesia and 3.7 for the tissue release portion of the procedure. For the follow-ups, 71% of subjects rated pain ≤ 3 at 3 days, and over 95% rated pain ≤ 3 thereafter. No subjects reported pain at the 2 year follow-up.

Conclusion Statements:

This 510(k) Premarket Notification is for updated labeling of the Cellfina System based on completion of the 2 year follow-up from the pivotal trial. The clinical data demonstrates that the Cellfina System is both safe and effective for long term improvement in the appearance of cellulite. In addition, this 510(k) also includes modifications to the design of the Cellfina System for manufacturability and ease of customer use. Through comprehensive bench testing it has been confirmed that these changes do not pose any new questions of safety, product output or efficacy.

As demonstrated through nonclinical and clinical tests, the Cellfina System is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K134010) which was cleared on April 14, 2014, and as such, is substantially equivalent.