



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 25, 2016

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

Re: K153677

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: January 29, 2016
Received: February 1, 2016

Dear Suzon 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 yours,

Jennifer R. Stevenson -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

Indications for Use

510(k) Number (if known)

K153677

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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10. 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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Suite 200
Mesa, AZ 85204

Contact Person: Suzon Lommel, Vice President Regulatory and Quality Affairs

Telephone: (408) 336-1761

Fax: (480) 619-4071

Submission Date: December 17, 2015

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): K150505

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, 15-use motor module (CM1).

Current 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 2 year of observation.

Substantial Equivalence Comparison:

	Predicate Device (K150505) Cellfina System	Subject Device Cellfina System	Equivalence Discussion
Regulation	878.4790	878.4790	Same
Product Code	OUP	OUP	Same
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 2 years 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.	Same
Where Used	Clinic/doctor's office	Clinic/doctor's office	Same
Anatomical Site	Buttocks and thighs	Buttocks and thighs	Same
Type of Energy/Mechanism of Action	Mechanical movement driven by battery operated motor module	Mechanical movement driven by battery operated 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

	Predicate Device (K150505) Cellfina System	Subject Device Cellfina System	Equivalence Discussion
Patient Contact Material	Biocompatible	Biocompatible	Same
EMC/Safety Standards	Compliant 60601-1 60601-1-2	Compliant 60601-1 60601-1-2	Compliance to IEC 60601-1 and IEC 60601-1-2
Sterile Barrier/Packaging - CK1	<ul style="list-style-type: none"> • Single thermoformed tray with a Tyvek sealed outer tray. • Foam insert within outer corrugated shipper • Outer corrugated shipper 	<ul style="list-style-type: none"> • Single thermoformed tray with a Tyvek sealed outer tray. • Foam insert within outer corrugated shipper • Outer corrugated shipper 	Same
Shelf Life - CK1	6 months	12 months	CK1 shelf life extension from 6 months to 12 months; shelf life and packaging testing demonstrates stability of CK1 out to 12 months of shelf life
Motor Module Device Design	2 piece plastic enclosure to eliminate seams and remove possibly difficult to disinfect areas around the toggle switch. A single LED push button on/off switch located on as switch PCB underneath; 15 uses	2 piece plastic enclosure to eliminate seams and remove possibly difficult to disinfect areas around the toggle switch. A single LED push button on/off switch located on as switch PCB underneath; 15 uses	Same

Non-clinical Performance Data:

The subject device of this Special 510(k) submission was tested to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* and was found to be in compliance with the requirements of this standard. Additionally, ship testing, simulated use, structural integrity, verification of physical characteristics and primary functionality on 12 month aged product demonstrates that the CK1 disposable kit is stable out to 12 months of shelf life. All other non-clinical tests required per the Special Controls (biocompatibility, sterility, EMC, bench testing, etc.), are provided within the predicate device under K150505 and remain applicable to this Special 510(k) submission; see the 510(k) summary for K150505 for additional information.

In-vivo Testing:

The in-vivo evaluation (clinical trial data) information provided within the predicate device under K150505 is applicable to this Special 510(k) submission; see the 510(k) summary for K150505 for additional information.

Conclusion:

This Special 510(k) Premarket Notification is for an extension of shelf life (from 6 months to 12 months) for the sterile, single-use, disposable kit (CK1), and for labeling changes required for compliance to IEC 60601-1, 3rd Edition. These changes do not alter the device design and do not pose any new questions of safety, product output or efficacy. As demonstrated through bench testing, the subject device Cellfina System is as safe, as effective, and performs as well as the legally marketed predicate device (K150505), and as such, is substantially equivalent.