K092195

Attachment 8
510(k) Summary for the
Cutera CMMCD

OCT - 1 2009

I. General Information

Submitter: Cutera, Inc. – 510(k) owner
3240 Bayshore Blvd
Brisbane, CA 94005

Contact Person: Kathy Maynor, VP of Regulatory/Quality

Telephone: 415-657-5586
Cell phone: 352-586-3113
Fax: 415-330-2443

Summary Preparation Date: July 1, 2009

II. Names

Device Proprietary Name: Cutera CMMCD

Primary Classification Name: Massager, Vacuum, Light Induced Heating – assigned to 21 CFR 878.4810 (Laser surgical instrument for use in general and plastic surgery and in dermatology). The Product Code is NUV.

Common Name: Massager, Vacuum, Light Induced Heating

III. Predicate Devices

- K082622 Alma Lasers Accent Uniform Massager Handpiece

IV. Product Description/Technological Characteristics

The Cutera CMMCD treatment consists a massage device and an infrared light(optional)/RF device. Topical heating for the purpose of elevating tissue temperature is derived from conducted RF energy/optional infrared light. Mechanical manipulation is derived from a vacuum assisted massage with rollers. The pneumatic/mechanical manipulation of the skin is sufficient to provide mild transient erythema and produces a temporary improvement in the appearance of cellulitic skin where applied.

V. Statement of Intended Use

The Cutera CMMCD optional infrared/RF device is indicated for the relief of minor muscle aches and pains, relief of muscle spasms, temporary improvement in local circulation. The Cutera CMMCD massage device is indicated for the temporary improvement in the appearance of cellulite.

VI. Rationale for Substantial Equivalence

The performance and technical specification changes to the CMMCD fall within the FDA regulations for the special 510(k). A discussion of the changes was provided as well as an additional predicate device.

VII. Safety and Effectiveness Information

Technologically, the Cutera CMMCD is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the Cutera CMMCD are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised.

VIII. Conclusion

The Cutera CMMCD, as modified by this special 510(k), does not raise any new issues regarding safety or effectiveness, and therefore is suitable for sale as a prescription medical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Cutera, Inc.
% Ms. Kathy Maynor
VP of Regulatory/Quality
3240 Bayshore Boulevard
Brisbane, California 94005

OCT - 1 2009

Re: K092195
Trade/Device Name: Cutera CMMCD
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: NUV, GEI, ISA
Dated: August 25, 2009
Received: September 1, 2009

Dear Ms. Maynor:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K092195

Device Name: **Cutera CMMCD**

Indications For Use:

The Cutera CMMCD infrared(optional) and RF energies are intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

The Cutera CMMCD massage device is intended to provide a temporary reduction in the appearance of cellulite.

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092195