K080300

Attachment 14
510(k) Summary for the
Cutera CMMCD

APR - 8 2008

I. General Information

Submitter:	Cutera, Inc. – 510(k) owner 3240 Bayshore Blvd Brisbane, CA 94005
Contact Person:	Kathy Maynor, Acting VP of Regulatory/Quality
Telephone:	415-657-5586
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Summary Preparation Date:	January 29, 2008

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

- K050397 Velasmooth manufactured by Syneron Medical Ltd.
- K070092 Velasmooth manufactured by Syneron Medical Ltd
- K071872 Velashape manufactured by Syneron Medical Ltd
- K030876 Triactive manufactured by Cynosure Corporation
- K990445 LPG Therapeutic Massager by LPG Systems

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 Cutera CMMCD has the same or similar indications for use as the listed predicate devices, and is also technologically substantially equivalent to the listed predicate devices. There are no new questions of safety or effectiveness raised by the introduction of this device. No clinical data was needed to prove substantial equivalence.

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 by the introduction of this device.

VIII. Conclusion

The Cutera CMMCD was found to be substantially equivalent to currently marketed Velasmooth/Velashape, Triactive, and LPG Endermologie devices. The Cutera CMMCD shares similar indications for use, design features, and similar functional features as these devices, and thus is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR - 8 2008

Re: K080300
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: II
Product Code: NUV
Dated: March 20, 2008
Received: March 24, 2008

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological 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): _____

Device Name: **Cutera CMMCD**

Indications For Use:

The Cutera CMMCD infrared 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. Ogden for MRM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080300