K 070138

Attachment 5
510(k) Summary for the
Cutera Er:YAG Laser System

MAR 2 7 2007

I. General Information

Submitter: Cutera, Inc.
3240 Bayshore Blvd
Brisbane, CA 94010

Contact Person: Connie Hoy

Telephone: 415-657-5586
Fax: 415-330-2443

Summary Preparation Date: January, 15, 2007

II. Names

Device Proprietary Name: Cutera Er:YAG Laser Handpiece

Classification Name: Instrument, Powered, Laser, GEX

Common Name: Dermatology Laser

III. Predicate Devices

- K060033 Sciton Profile Er:YAG
- K032599 MLT Erbium:YAG

IV. Product Description/Technological Characteristics

The Cutera Er:YAG Laser handpiece is an optional handpiece for the currently marketed Xeo and Solera Opus laser systems. The handpiece emits laser energy at a wavelength of 2940nm. The water cooled laser is located in the handpiece and utilizes a computer controlled scanner.

V. Statement of Intended Use

The Cutera Er:YAG Laser System is designed for use in applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue including treatment of wrinkles and skin resurfacing.

VI. Rationale for Substantial Equivalence

The Cutera Er:YAG Handpiece shares the same general indications for use as the currently marketed predicate devices, and does not raise any issues with safety and effectiveness. There are no unique applications, indication, materials or specification presented in this application. The Cutera Er:YAG Handpiece is therefore substantially equivalent to the currently marketed predicate devices.

VII. Safety and Effectiveness Information

Technologically, the Cutera Er:YAG Handpiece is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the Cutera Er:YAG Handpiece are comparable to the predicate devices.

Cutera therefore believes that there are no new questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The Cutera Er:YAG Handpiece was found to be substantially equivalent to currently marketed devices. The Cutera Er:YAG shares similar indications for use, design features, and similar functional features as the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2007

Cutera, Inc.
% Ms. Connie Hoy
VP of RA/QA
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K070138
Trade/Device Name: Cutera ER:YAG Laser Handpiece
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: GEX
Dated: January 15, 2007
Received: January 19, 2007

Dear Ms. Hoy:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

for

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

Enclosure

Attachment 4
Indications For Use Statement

510(k) Number (if Known): K070138

Device Name: **Cutera Er:YAG Laser Handpiece**

Indications for Use:

The Cutera Er:YAG Laser Handpiece is designed for use in applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue.

Indications include: treatment of wrinkles and skin resurfacing.

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

510(k) Number K070138

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____