OCT 18 2004

K042165 p1/2

Premarket Notification 510(k) Submission:
Cutera Titan Tabletop Product

Attachment 12
510(k) Summary for the
Cutera Titan Tabletop Product

I. General Information

Submitter:	Cutera, Inc. 3240 Bayshore Boulevard Brisbane, CA 94005
Contact Person:	Kathy Maynor
Summary Preparation Date:	September 17, 2004

II. Names

Device Names:	Cutera Titan Tabletop Product
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Cutera Optional Infrared Handpiece

IV. Product Description

The Cutera Titan Tabletop Product consists of a modified console designed to drive the infrared handpiece, which is an existing, FDA cleared attachment for the existing, FDA cleared laser. The handpiece is an infrared handpiece with a variable emission of 0.8 to 2.0 microns (850 – 3000 nm). The delivered wavelength is filtered to 1100nm – 1800nm via coated glass filters to eliminate the extraneous wavelengths.

The Cutera Titan Tabletop Product is comprised of five main components:

- a system console (including software and control electronics);
- a control and display panel;
- a detachable handpiece with integrated skin cooling;
- a foot-operated exposure switch (footswitch); and
- a remote interlock connector (disables emission when treatment room door is opened).

The proximal end of the umbilical cable is semi-permanently attached to the laser system console and the distal end is permanently attached to the body of the delivery hand piece. This hand piece is removable by either the user or an authorized field service engineer for replacement at the proximal end.

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V. Indications for Use

The Cutera Titan Tabletop Product with an infrared handpiece is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Cutera Titan Tabletop Product may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

VI. Rationale for Substantial Equivalence

The Cutera Titan Tabletop Product shares the same general indications for use, and therefore is substantially equivalent to the currently cleared infrared handpiece (K033768) and the currently cleared base console (K023954).

VII. Safety and Effectiveness Information

The **indication for use** is exactly the same as the previously cleared infrared handpiece (K033768).

Technologically, the Cutera Titan Tabletop Product is substantially equivalent to the listed predicate device. Therefore the risks and benefits for the Cutera Titan Tabletop Product 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 Titan Tabletop Product was found to be substantially equivalent to the currently cleared infrared handpiece (K033768) and base console (K023954). The Cutera Titan Tabletop Product shares similar indications for use, design features, and similar functional features as, and thus are 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

OCT 18 2004

Cutera, Inc.
c/o Mr. Morten S. Christensen
FDA Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K042165
Trade/Device Name: Cutera Titan Tabletop Product
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: September 28, 2004
Received: September 29, 2004

Dear Mr. Christensen:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K042165

Device Name: **Cutera Titan Tabletop Product**

Indications For Use:

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Prescription Use √ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

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