K122493

Attachment 6
510(K) Summary
Cutera GenesisPlus Laser System

MAY 15 2013

This 510(K) Summary of safety and effectiveness for the Cutera GenesisPlus Laser is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cutera, Inc.
Address:	3240 Bayshore Blvd. Brisbane, CA 94005
Contact Person:	Connie Hoy
Telephone: Fax: Email:	415-657-5592 – phone 415-715-3592 – fax choy@cutera.com
Preparation Date:	August 10, 2012
Device Trade Name:	Cutera GenesisPlus Laser System
Common Name:	Nd:YAG Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Cutera GenesisPlus under K103626
Description of the Cutera GenesisPlus Laser:	The Cutera GenesisPlus Laser unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. Laser energy produced within the device is delivered to the tissue by means of a handpiece using a fiber optic delivery system with an optical lens at the aperture. . The user activates laser emission by means of a footswitch. The Cutera GenesisPlus Laser is designed to provide laser energy for use in a variety of dermatology and podiatry procedures.
Intended use of the Cutera GenesisPlus Laser System:	The Cutera GenesisPlus Nd:YAG laser is intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic.laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary.thoracic surgery, podiatry and urology for surgical and aesthetic applications.

Specific Indications:

Dermatology:

The Cutera GenesisPlus laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, rosacea/ diffuse redness, poikiloderma of civatte, scar reduction (including hypertropic and keloid scars), and warts.

The Cutera GenesisPlus laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The GenesisPlus laser is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

Podiatry:

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

The Cutera GenesisPlus laser is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

Performance Data: None

Results of Clinical Study: A clinical study was conducted to evidence that the change to the treatment parameters for the podiatry indication is safe and effective. The study demonstrated safety and effectiveness for use for the temporary increase of clear nail.

Summary of Technological Characteristics:

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Comparison of Technical Specification for Dermatology indications for use:

Features	Cutera GenesisPlus Laser (K)103626)	Cutera GenesisPlus Laser (revised)
Wavelength	1064nm Nd:YAG	1064nm Nd:YAG
Aiming Beam	630-680nm (≤ 2.5mW)	630-680nm (≤ 2.5mW)
Energy per Pulse	20-3500 mJ	20-3500 mJ
Fluence	25.5J/cm2 (with 1mm spot)	25.5J/cm2 (with 1mm spot)
Power	≤ 100W	≤ 100W
Spot Size	Up to 13mm	Up to 13mm
Pulse Duration	100-3000µs	100-3000µs
Output mode	Pulsed	Pulsed
Repetition Rate	5-100 Hz	5-100 Hz
Laser Media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
User Interface	LCD color touchscreen	LCD color touchscreen

Comparison of Technical Specification for temporary increase of clear nail indication for use:

Features	Cutera GenesisPlus Laser (K)103626)	Cutera GenesisPlus Laser (revised)
Wavelength	1064nm Nd:YAG	1064nm Nd:YAG
Aiming Beam	630-680nm (≤ 2.5mW)	630-680nm (≤ 2.5mW)
Fluence	25.5J/cm2 (with 1mm spot)	15-18 J/cm2
Power	≤ 100W	≤ 100W
Spot Size	1.0-1.5mm	5mm
Pulse Duration	100µs	0.3ms
Output mode	Pulsed	Pulsed
Repetition Rate	20 Hz	2-3Hz
Burst Mode Sequence	½ second on ½ second off	Not applicable
Laser Media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
User Interface	LCD color touchscreen	LCD color touchscreen
Laser activation	Footswitch	Footswitch
Delivery Devices (How Supplied)	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable

Conclusion:

The Cutera GenesisPlus Laser is substantially equivalent to the previously cleared Cutera GenesisPlus Laser (K103626). The Cutera GenesisPlus Laser is substantially equivalent in terms of indication for use and technology based on technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Cutera, Inc.
% Ms. Connie Hoy
3240 Bayshore Boulevard
Brisbane, California 94005

May 15, 2013

Re: K122493
Trade/Device Name: Cutera GenesisPlus Laser System
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: PDZ; GEX
Dated: April 22, 2013
Received: April 23, 2013

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. 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 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/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 Small Manufacturers, International and Consumer Assistance 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,

FOR Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K 122493

Device Name : Cutera GenesisPlus Laser System

Indications for Use:

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Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.05.09 15:16:48 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K122493