K103626

Attachment 5
510(K) Summary
Cutera GenesisPlus Laser System

APR - 5 2011

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:	November 24, 2010
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 Nd:YAG Laser K022226 PinPointe Footlaser K09354 and K093545
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:	None
Summary of Technological Characteristics:	

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Features	Cutera GenesisPlus Laser	PinPointe Footlaser K09354, K083545	Cutera Nd:YAG Laser K022226
Wavelength	1064nm Nd:YAG	1064nm Nd:YAG	1064nm Nd:YAG
Aiming Beam	630-680nm (≤ 2.5mW)	630-680nm (≤ 2.5mW)	none
Energy per Pulse	20-3500 mJ	20 – 3500 mJ	≤ 3500mJ
Fluence	25.5 J/cm2 (with 1mm spot)	25.5 J/cm2 (with 1mm spot)	Up to 25,000J/cm2 (with 0.1mm spot)
Max Power	≤ 100W	≤100W	≤100W
Pulse Duration	100 - 3000µs	100 – 3000 µs	≤ 300ms
Spot Size	1 mm (for Podiatry) Up to 13mm (other indications)	1mm (for podiatry) Other spot sizes are not published	0.1 – 13mm
Output mode	Pulsed	Pulsed, multimode	Pulsed
Repetition Rate	5 – 100 Hz	5 – 100 Hz	Single shot and up to 10 Hz
Laser Media	Flashlamp pumped solid state rod	Flashlamp pumped solid state laser rod	Flashlamp pumped solid state rod
User Interface	LCD color touchscreen	LCD color touch screen or push-button control panel	Push button control or LCD color touchscreen

Conclusion:

The Cutera GenesisPlus Laser is substantially equivalent to the Cutera Nd:YAG Laser (K022226) and to the PinPointe Footlaser (K09354 and K083545). 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 20993-0002

May 13, 2013

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

Re: K103626
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: March 24, 2011
Received: March 25, 2011

Dear Ms. Hoy:

This letter corrects our substantially equivalent letter of April 5, 2011.

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 contact 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. 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 103626

Device Name : Cutera GenesisPlus Laser System

Indications for Use:

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.

Dermatology:

The Cutera GenesisPlus laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, rosacea, poikiloderma of civatte,, and treatment of benign cutaneous lesions, such as warts, scars and straie. The laser is also intended for the treatment of benign pigmented lesions.

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.).

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103626