K132185

CUTERA

SAN FRANCISCO HEADQUARTERS
3240 Bayshore Boulevard, Brisbane, CA 94005
Phone 415-657-5500 | Fax: 415-330-2444 | www.cutera.com

Attachment 5
510(K) Summary
Family of CoolGlide Aesthetic Lasers

This 510(K) Summary of safety and effectiveness for the Family of CoolGlide Aesthetic Lasers 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:	Sandra Hansen
Telephone: Fax: Email:	415-657-5526 – phone 415-715-3526 – fax shansen@cutera.com
Preparation Date:	December 3, 2013
Device Trade Name:	Family of CoolGlide Aesthetic Lasers
Common Name:	Dermatology Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Handpiece (K023954) Candela GentleMAX Family of Laser Systems (K112715)
Description of the Family of CoolGlide Aesthetic Lasers:	The Cutera Family of CoolGlide Aesthetic Lasers comprises a variety of laser and non-laser light sources, including single wavelength (755 nm Alexandrite, 1064 nm Nd:YAG or 532 nm Nd:YAG), multiple wavelength, pulsed light, and laser/pulsed light combination models. The Family of CoolGlide Aesthetic Lasers treats a wide range of dermatologic conditions requiring selective photothermolysis of target chromophores. The Family of CoolGlide Aesthetic Lasers consists of a system console, permanently attached laser handpiece, footswitch, handpiece resting tree, and detachable pulsed light handpieces.

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Intended use of The Family of CoolGlide Aesthetic Lasers:

The Family of CoolGlide Aesthetic Lasers is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

Specific Indications:

755 nm:

The Family of CoolGlide Aesthetic Lasers is indicated for temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime.

The Family of CoolGlide Aesthetic Lasers is also indicated for:

- treatment of benign pigmented lesions
- treatment of wrinkles
- photocoagulation of dermatological vascular lesions such as, but not limited to, port wine stains, hemangiomas and telangiectasias

1064 nm:

Dermatology:
The Family of CoolGlide Aesthetic Lasers is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as, but not limited to, warts, scars, striae and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

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The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The CoolGlide lasers are indicated for temporary and permanent hair reduction. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime.

The CoolGlide lasers are also indicated for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the CoolGlide laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:

The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

532 nm:

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasias (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment

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(hemostasis, color lightening, blanching, flattening, reduction of lesion size).

Optional Pulsed Light Handpiece:

For the treatment of benign pigmented lesions.

Performance Data:	IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance Software Verification and Validation Testing Reports V0066 r1 Alexandrite- Xeo 510K V&V 4.6.0 V0066 r2 Alexandrite- Xeo 510K V&V 5.0
Results of Clinical Study:	None
Summary of Technological Characteristics:	See Below:

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Technical Specification Comparison

	Family of CoolGlide Aesthetic Lasers	Candela GentleMAX Family of Laser Systems (K112715)†	Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Handpiece (K023954)
Wavelengths	755 nm Alexandrite laser 1064 Nd:YAG laser 532 nm Nd:YAG laser 500–1300 nm pulsed light	755 nm Alexandrite laser 1064 nm Nd:YAG laser	1064 Nd:YAG laser 532 nm Nd:YAG laser 500–1300 nm pulsed light
Fluence	755 nm: 4–100 J/cm² 1064 nm: 3–300 J/cm² 532 nm: 1.8–42 J/cm² 500–1300 nm: 2–65 J/cm²	755 nm: 3–100 J/cm² 1064 nm: 3–520 J/cm²	1064 nm: ≤ 25,000 J/cm² (with 0.1 mm spot) 532 nm: ≤ 25,000 J/cm² (with 0.1 mm spot) 500–1300 nm: 2–65 J/cm²
Pulse Duration	755 nm: 3 ms 1064 nm: 0.1–300 ms 532 nm: 1.5–40 ms 500–1300 nm: 0.5–100 ms	755 nm: 0.25–100 ms 1064 nm: 0.25–100 ms	1064 nm: ≤ 990 ms 532 nm: ≤ 990 ms 500–1300 nm: 0.5–100 ms
Spot Size	755 nm: 5, 8, 10, 12, 15 and 18 mm 1064 nm: 3, 5, 8, 10 and 12 mm 532 nm: 2–12 mm 500–1300 nm: 30 x 10 mm	755 nm: 1.5-24 mm 1064 nm: 1.5-24 mm	1064 nm: 0.1–50 mm 532 nm: 0.1–50 mm 500–1300 nm: 30 x 10 mm
Output Mode	Pulsed	Pulsed	Pulsed
Repetition Rate	755 nm: ≤ 2 Hz and single shot 1064 nm: ≤ 10 Hz and single shot 532 nm: ≤ 4 Hz and single shot 500–1300 nm: ≤ 1 Hz and single shot	755 nm: ≤ 10 Hz and single shot 1064 nm: ≤ 10 Hz and single shot	1064 nm: ≤ 100 Hz and single shot 532 nm: ≤ 100 Hz and single shot 500–1300 nm: ≤ 1 Hz and single shot
Laser Media	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod
User Interface	Push button control or LCD color touchscreen	Push button control or LCD color touchscreen	Push button control or LCD color touchscreen
Treatment Beam Activation	Footswitch	Footswitch or fingerswitch	Footswitch
Skin Cooling	Full contact thermoelectric chiller	Air cooling or optional cryogen cooling	Full contact thermoelectric chiller
Aiming Beam	755 nm: 630–680 nm 1064 nm: 630–680 nm 532 nm: 630–680 nm 500–1300 nm: none	755 nm: 635-670 nm 1064 nm: 520-550 nm	1064 nm: 630–680 nm 532 nm: 630–680 nm 500–1300 nm: none
Delivery Devices (How Supplied)	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable
Optional Detachable Handpieces	Yes	unknown	Yes

† Candela technical specifications taken from GentleMAX product webpage (http://syneron-candela.com/na/product/gentle-pro-series/howitworks)

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Conclusion: Based on performance testing results and a comparison of technical specifications, intended uses and indications for use, the Family of CoolGlide Aesthetic Lasers has been shown to be substantially equivalent to the Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulsed Light Handpiece (K023954) and to the Candela GentleMAX Family of Laser Systems (K112715).

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

Cutera Incorporated
Ms. Sandra Hansen
Regulatory Affairs Manager
3240 Bayshore Boulevard
Brisbane, California 94005

December 6, 2013

Re: K132185
Trade/Device Name: Family of CoolGlide Aesthetic Lasers
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: GEX
Dated: November 7, 2013
Received: November 8, 2013

Dear Ms. Hansen:

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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132185

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden -S
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(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number _K132185_____

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Optional Pulsed Light Handpiece:
For the treatment of benign pigmented lesions.

Prescription Use __X_ AND/OR Over-The-Counter Use _____
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number __K132185_____