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CANDELA

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness for the Candela GentleYAG Family of Laser Systems is being submitted in accordance with the requirements of the SMDA 1990, 21 CFR 807.92 and follows the guidance concerning the organization and content of a 510(k) summary.

I. General Information

Applicant:	Candela Corporation
Address:	530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Calzetta Patrovic Manager, Regulatory Affairs
Date Prepared:	August , 2003

II. Names

Device Trade Name:	GentleYAG Family of Laser Systems
Common Name	Dermatology Laser
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)

III. Predicate Devices

Candela GentleYAG a.k.a Long Pulse Nd:YAG Laser (K010104, K0022923. K022951, K023193), Lyra I (K020021,K003765, K003147) Altus CoolGlide Family of Lasers (K023954, K010834,K003765)

IV. Product Description

The Candela *GentleYAG* Family of Laser Systems is a flashlamp-excited, Nd: YAG(Neodymium-doped Yttrium Aluminum Garnet) laser. Pulsed laser energy at a nominal wavelength of 1064 nanometers (nm) is used. This wavelength causes maximum energy absorption by the target (hair or lesion) and minimum absorption by surrounding skin structures. In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues.

The GentleYAG consists of the following main components:
a laser system console (including software and control electronics)
a control and display panel
a lens-coupled, user replacement optical fiber handpiece with aiming beam
a footswitch or handswitch
a remote interlock connector
an optional cooling device

V. Indications for Use
The GentleYAG Family of Laser Systems is intended for:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicted on all skin types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions. such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, Venus lake leg veins and spider veins

Coagulation and hemostasis of soft tissue.

Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe 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. The laser is 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. The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles

VI. Rationale for Substantial Equivalence
The Candela GentleYAG Family of Laser Systems shares the same indications for use, operating principles, mechanism of action, technological features as the predicate devices and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information
The Candela GentleYAG Laser Family of Laser Systems is equivalent to the Candela GentleYAG (aka Candela Long Pulse Nd: YAG Laser) cleared under K010104, K022923,K022951,K023193 the Lyra I (K020021,K003765, K003147) and the Altus CoolGlide Family of Lasers (K023954, K010834,K003765) in technological features, and equivalent in intended use and therefore the risks and benefits are comparable to the predicate devices. Candela Certifies that this device is in compliance with the laser performance standards required as per 21 CFR 1000.1040. The device conforms to the UL 2601 Electrical Safety Standard and with the Harmonized Standard EN 60601-1-2, Part 2 established by the European Community. We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the GentleYAG Family of Laser Systems.

VIII. Conclusion
It is the opinion of Candela Corporation that the GentleYAG Family of Laser Systems is substantially equivalent to the predicate devices based on operating principles mechanism of action, and for intended use.

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Statement of Substantial Equivalence

The purpose of this 510(k) submission is to obtain clearance to market the Candela Gentle YAG Family of Laser Systems.

The Candela GentleYAG Family of Laser Systems presented in this submission, is a modification of the Candela GentleYAG Laser System a.k.a Candela Long Pulse Nd: YAG previously cleared under K010104, K022951, K022923, K023193.

The modifications incorporate features of the currently marketed predicate devices, including expanded pulse durations, pulse frequencies, spot sizes, energy and indications for use. The Table of Comparative Features (included as Exhibit D) shows the features of the devices, including their similarities.

As indicated in the table, the GentleYAG Famly of Laser Systems is equivalent to the currently marketed predicate devices, the Laserscope Lyra I Nd: YAG Laser (cleared under K020021, K0037565, K 0031747), and the Altus Cool Glide Family of Lasers (cleared under K023954, K010834, K003765), based on operating principles, mechanism of action, and shares similar functional features such as wavelength, pulse duration, pulse frequency, energy, spot sizes, and indications for use. Therefore, we do not believe that introduction of the modified GentleYAG Family of Laser Systems raises any new issues of safety or effectiveness.

In conclusion, Candela believes that the GentleYAG family of Laser Systems is 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 3 0 2003

Ms. Lorraine Calzetta Patrovic
Manager, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778-1886

Re: K033172
Trade/Device Name: Candela GentleYAG Family of Laser Systems
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: September 26, 2003
Received: September 30, 2003

Dear Ms. Patrovic:

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 (301) 594-4659. 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

CANDELA

INDICATIONS FOR USE STATEMENT

510(k) Number : K033172

Device Name: Candela GentleYAG Family of Laser Systems

Indications For Use:

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Treatment of wrinkles.

(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

510(k) Number K033172

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)