



MAR 13 2003

K022923

**510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) Summary of Safety and Effectiveness for the Candela GentleYAG Laser System 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 Nelson  
Manager, Regulatory Affairs  
Date Prepared: August 22, 2002

**II. Names**

Device Trade Name: GentleYAG Laser System  
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 Long Pulse Nd:Yag Laser (K010104)  
Altus Family of Cool Glide Lasers (K014040)

**IV. Product Description**

The GentleYAG laser 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
- a skin cooling device integrated into the handpiece
- a footswitch or handswitch
- a remote interlock connector

## **V. Intended Use**

The GentleYAG Laser is intended for use in the treatment of :

- 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.
- 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.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Removal of unwanted hair in skin types I to VI
- Photocoagulation and hemostasis of pigmented and vascular lesions
- Coagulation and hemostasis of soft tissue.

## **VI. Rationale for Substantial Equivalence**

The Candela GentleYag Laser shares the same indications for use, matches key design aspects, including spot size, similar wavelength and/or the same maximum delivered power as the predicate devices, and therefore are substantially equivalent to the currently marketed Candela Long Pulse Nd: YAG Laser System (K010104) and the Altus Family of Cool Glide Lasers (K014040).

## **VII. Safety and Effectiveness Information**

The new indications for use are based on the indications for use for the predicate laser systems.

Technologically, the Candela GentleYAG Laser is identical to the previous predicate Candela Long Pulse Nd: YAG Laser (K010104), therefore the risks and benefits for the GentleYAG Laser are comparable to this predicate device.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the device.

## **VIII. Conclusion**

Candela believes that the GentleYAG Laser System is substantially equivalent to the predicate devices based on operating principles, materials, mechanism of action, design, construction, methods of assembly and intended uses.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 13 2003

Candela Corporation  
Lorraine Nelson  
Manager, Regulatory Affairs  
530 Boston Post Road  
Wayland, Massachusetts 01778-1886

Re: K022923

Trade/Device Name: Gentle YAG Laser System  
Regulation Number: 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: September 3, 2002  
Received: September 4, 2002

Dear Ms. Nelson:

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

Page 2 – Ms. Lorraine Nelson

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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., MD  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**INDICATION FOR USE STATEMENT**

510(k) Number (if known): K022923

Device Name: Candela Corporation GentleYAG Laser System

Indications For Use:

The Candela GentleYAG Laser is intended for use for:

- 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.
- 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.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use 7  
(Per 21 CFR 801.109)

510(k) <sup>OR</sup> Number K022923 Over-The-Counter Use \_\_\_\_\_