AUG 1 3 2004

Attachment I
510(K) Summary
DuraLITE-GL

K 041262

This 510(K) Summary of safety and effectiveness for the DuraLITE-GL 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:	Laser Scientific
Address:	Laser Scientific 115 Sundance Parkway # 230B Round Rock, TX 78681
Contact Person:	Mr. John Crownover
Telephone:	1-512-733-8709
Preparation Date:	May 1, 2004
Device Trade Name:	DuraLITE-GL
Common Name:	Accessory to a Laser Device
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	GentleLASE Plus Fiber Optic cleared under K024371, K024260, K024335, K994260, K984601K003460
Description of the DuraLITE-GL	The DuraLITE-GL is an exact replacement component for the Candela GentleLASE Plus fiber optic.
Intended use of the DuraLITE-GL	The DuraLite-GL is a replacement fiber optic component for the Candela GentleLASE family of lasers. The DuraLite-GL may be used as a replacement part for all procedures as cleared by the FDA for the Candela GentleLase family of lasers.
Performance Data:	Physical, Optical, Connectivity and Environmental testing have been performed. Testing validates that the performance of the DurLite-GL I identical to the fiber optic components manufactured by Candela for the GentleLase family of lasers.
Results of Clinical Study:	None
Conclusion:	The DuraLITE-GL is substantially equivalent to other existing fiber optics components in commercial distribution for use in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2004

Mr. John Crownover
General Manger
Laser Scientific
115 Sundance Parkway, #230B
Round Rock, Texas 78681

Re: K041262
Trade/Device Name: DuraLite-GL
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: May 1, 2004
Received: May 17, 2004

Dear Mr. Crownover:

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

Indications for Use

510(k) Number (if known): K041262

Device Name: DuraLite-GL

Indications For Use:

The DuraLite-GL is a replacement fiber optic component for the Candela GentleLASE family of lasers.

The DuraLite-GL may be used as a replacement part for all procedures as cleared by the FDA for the Candela GentleLase family of lasers.

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)

Miriam C. Provost

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

510(k) Number K041262