

VII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:

From a technology perspective, theory of operation the predicate device is the same as the Schwartz Electro-Optics, Inc. CRL 2940 Erbium CrystaLase. The laser mediums are the same, the systems are similar both mechanically and electronically. Schwartz Electro-Optics, Inc. believes that the technological characteristics of the TriLase 2940 Erbium Laser are similar to the predicate device (Premier Centauri Erbium). The Premier Centauri Erbium has the ability to deliver laser energy at 2.94 microns (2940nm), average power of 5 watts at repetition rates of up to 50 pulses per second. These characteristics are very similar to the Schwartz Electro-Optics, Inc. TriLase 2940 Erbium Laser.

In regards to safety and effectiveness of the Schwartz Electro-Optics, Inc. TriLase 2940 Erbium Laser, Schwartz Electro-Optics, Inc. believes that the slight differences in the performance characteristics of these devices raises no concerns.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Timothy J. Shea
Director of the Solid State Laser Division
Schwartz Electro-Optics, Inc.
3404 North Orange Blossom Trail
Orlando, Florida 32804

JUL - 9 1997

Re: K971404
Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase
Regulatory Class: II
Product Code: GEX
Dated: April 16, 1997
Received: April 16, 1997

Dear Mr. Shea:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

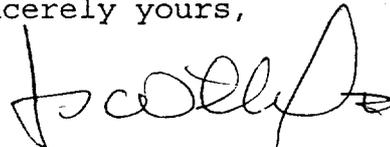
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



f. Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1971404

510(k) Number (if known): ~~K954613~~

Device Name: CLR 2940

Indications For Use: SEE ATTACHED

23 JUN 97 13 50
FDA/CDRH/ODE/DMC

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 1971404

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

SK-31

SEO Medical

Food and Drug Administration
Center of Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ - 401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: ~~K954013~~
K971404

Indication for Use

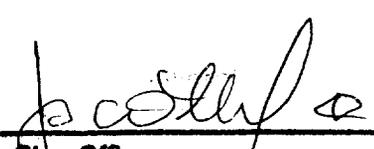
Schwartz Electro-Optics, Inc. is not requesting any additional indications or changing the indications as previously cleared in K954013 received 1/31/96. As previously cleared, the Schwartz Electro-Optics, Inc. CLR 2940 will be indicated for use in small and large joint Arthroscopy, including laparoscopic procedures, general and all surgical procedures for cutting (incision/excision), vaporizing, ablating and coagulating soft tissue and cartilage. All soft tissues encountered in all surgical procedures are included in this indication such as, skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Specialties are:

- | | |
|---------------------|----------------------------------|
| * General Surgery | * Dermatology |
| * Plastic Surgery, | * Gastroenterology |
| * Podiatry | * Ophthalmology |
| * Urology | * ENT |
| * Gynecology | * Thoracic Surgery |
| * Pulmonary Surgery | * Oral and Maxillofacial Surgery |

These indications have been cleared for marketing by the Food and Drug Administration for the cited predicated laser. Schwartz Electro-Optics, Inc. seeks *no new* indications for the CLR 2940 and is only requesting a modification.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

K971404