

K974039

JAN 12 1998

VIII. 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 CLR 2940 are similar to the predicate device, the Continuum Biomedical CB Erbium/2.94.

In regards to safety and effectiveness of the Schwartz Electro-Optics, Inc. CLR 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

JAN 12 1998

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

Re: K974039
Trade Name: Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase
Regulatory Class: II
Product Code: GEX
Dated: October 16, 1997
Received: October 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.

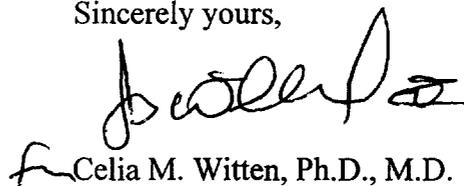
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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,



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

K974039

RECEIVED

Food and Drug Administration

Office of Device Evaluation
Document Mail Center (HFZ - 401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Oct 16 10 54 AM '91
FDA/CDRH/ODE/DMC

~~Reference: K974039~~

Indication for Use

As previously cleared, the Schwartz Electro-Optics, Inc. CLR 2940 is 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. The CLR 2940 may also be used for skin resurfacing and the treatment of wrinkles.

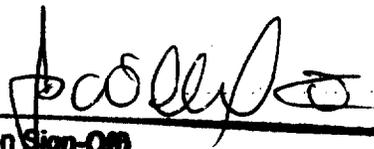
Specialties are:

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

These indications have been cleared for marketing by the Food and Drug Administration for the cited predicated lasers. Schwartz Electro-Optics, Inc. is simply requesting the addition of skin resurfacing and the treatment of wrinkles.

Prescription Use _____
(Per 21 CFR 801.109)

X



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

K974039

5/16/91