K980313

MAR 19 1998

510(k) Summary of Safety and Effectiveness
The Schwartz Electro-Optics, Inc. Model CLR 2940 Erbium CrystaLase

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the following: the Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase (K974039) and the Sharplan 4020 Erbium Surgical Laser (K971648).

I. Company: Schwartz Electro-Optics, Inc.
3404 North Orange Blossom Trail
Orlando, FL 32804
Timothy J. Shea, Senior Director
1/15/98

II. Model: Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase

III. Predicate Devices: Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase (K974039), and the Sharplan 4020 Erbium Surgical Laser (K971648).

IV. Description: The Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase is a medical device which is capable of emitting a pulsed treatment laser beam at a wavelength of 2940 nm under the guidance of a visible aiming beam. This laser may be used in a pulsed mode at various repetition rates.

V. Indications for Use: The Schwartz Electro-Optics, Inc. CLR 2940 is indicated for 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. These indications have been cleared for marketing by the Food and Drug Administration for the cited predicated lasers. No new indications were sought in this premarket notification and no clinical data was presented.

VI. Summary: From a design and clinical perspective, the predicate and candidate laser devices, are of the same technology and have the same intended use. Based upon an analysis of the overall performance characteristics for the devices, Schwartz Electro-Optics, Inc. believes that no significant differences exist. Therefore, the Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase should not raise any concerns regarding its overall safety and/or effectiveness.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

Mr. Timothy J. Shea
Senior Director
Schwartz Electro-Optics, Incorporated
3404 North Orange Blossom Trail
Orlando, Florida 32804

Re: K980313
Trade Name: Schwarts Electro-Optics, Inc. CLR 2940 Erbium CrystaLase
Regulatory Class: II
Product Code: GEX
Dated: January 27, 1998
Received: January 27, 1998

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 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,

for Stephen Rhodes

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

K980313

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

Schwartz Electro-Optics, Inc.
CLR 2940 Erbium CrystaLase
Indications 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.

Stephen Rhodes
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980313

Prescription Use X
(Per 21 CFR 801.109)

Over-the-Counter Use

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