MAY 22 1998

K 980710

SEO Medical
3414 N. Orange Blossom Trail • Orlando, FL 32804 • (407) 298-1802

510(k) Summary of Safety and Effectiveness
The Schwartz Electro-Optics, Inc. CrystaLase 755 DP

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

The safety and effectiveness of the Schwartz Electro-Optics, Inc. CrystaLase 755 DP is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the following: Cynosure, Inc. PhotoGenica LPIR; Candela Corporation AlexLazr.

I. Company: Schwartz Electro-Optics, Inc.
3404 North Orange Blossom Trail
Orlando, FL 32804

II. Model: Schwartz Electro-Optics, inc. CrystaLase 755 DP

III. Predicate Devices: Cynosure, Inc. PhotoGenica LPIR (K971737), Candela Corp. AlexLazr (K950831)

IV. Description: The Schwartz Electro-Optics, Inc. CrystaLase 755 DP System is a medical device which is capable of emitting a pulsed treatment laser beam at a wavelength of 755 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. CrystaLase 755 DP will be indicated for removal of tattoos of various types and colors, as well as epidermal, pigmented and vascular lesions. These indications have been cleared for marketing by the Food and Drug Administration for the cited predicate d 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 anlaysis of the overall performance characteristics for the devices, Schwartz Electro-Optics, Inc. believes that no significant differences exist. Therefore, the Schwartz Electro-Optics, Inc. CrystaLase 755 DP 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

MAY 22 1998

Mr. Matthew Assenmacher
Director of the Solid State Laser Division
Scwartz Electro-Optics, Incorporated
3404 North Orange Blossom Trail
Orlando, Florida 32804

Re: K980710
Trade Name: CrystaLase 755 DP
Regulatory Class: II
Product Code: GEX
Dated: February 24, 1998
Received: February 24, 1998

Dear Mr. Assenmacher:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Enclosures

510 (k) NUMBER (IF KNOWN): K980710

DEVICE NAME: CrystaLase 755 DP

INDICATIONS FOR USE:

The Schwartz Electro-Optics, Inc. CrystaLase 755 DP will be indicated for removal of tattoos of various types and colors, as well as epidermal, pigmented and vascular lesions. These indications have been cleared for marketing by the Food and Drug Administration for the cited predicated lasers. Schwartz Electro-Optics, Inc. seeks no new indications for the CrystaLase 755 DP laser system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980710