

K973867

**IX. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
SCHWARTZ ELECTRO-OPTICS, Inc.  
CRYSTALASE 755**

FEB 10 1998

From a technology perspective, theory of operation of all the aforementioned devices are all the same. While the laser mediums are identical, all the systems are similar both mechanically and electronically. Schwartz Electro-Optics, Inc. believes that the technological characteristics of the CrystaLase 755 are similar to the predicate lasers.

In regards to safety or effectiveness of the Schwartz Electro-Optics, Inc. CrystaLase 755, 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, Incorporated  
3404 North Orange Blossom Trail  
Orlando, Florida 32804

FEB 10 1998

Re: K973867  
Trade Name: Schwartz Electro-Optics, Inc. CrystaLase 755 Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: January 6, 1998  
Received: January 6, 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.

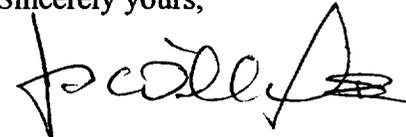
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

*C* 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

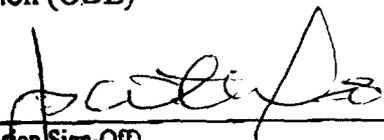
510(k) Number (If known): K 973867

Device Name: Schwartz Electro-Optics, Inc. CrystaLase 755

Indications for Use: The Schwartz Electro-Optics, Inc. CrystaLase 755 is indicated for removal of tattoos of various types and colors and benign epidermal pigmented lesions.

(Please Do Not Write Below This Line - Continue on Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973867

Prescription Use X

Or

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)