

K972099

AUG 27 1997

**510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Modified Ruby Laser System**

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 Sharplan Modified Ruby Laser System is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device which is the SLS Chromos 694 QD Ruby Laser System.

1. Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
George J. Hattub, Director of Regulatory Affairs/Quality Assurance
June 3, 1997
2. **Model:** Sharplan Model 5000 (Modified) EpiTouch Ruby Laser System
3. **Predicate Device:** The SLS Chromos 694 QD Ruby Laser System (K962109)
4. **Description:** The Sharplan Ruby Laser System is a surgical laser which is capable of providing pulsed laser energy of a 694.3 nm wavelength in the free running mode through an optical fiber beam delivery system. While observing and directing the aiming beam (633 nm, HeNe), the treatment beam is administered by the physician through a foot switch.
5. The Sharplan Ruby Laser System (*modified, with its fiber delivery system*) is intended for use in dermatology for the removal of unwanted dark body hair. No new indications were sought in this premarket notification. Therefore, no clinical data was presented.

**510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Modified Ruby Laser System
(continued)**

6. For the purpose of this 510(k) notification, 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, Sharplan Lasers, Inc. believes that no significant differences exist. Therefore, the modifications made to the Sharplan Ruby Laser System should not raise any concerns regarding its overall safety 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1997

Mr. George J. Hattub
Director of Regulatory Affairs/Quality Assurance, CQE
Sharplan Lasers, Inc.
1 Pearl Court
Allendale, New Jersey 07401

Re: K972099
Trade Name: Sharplan EpiTouch Ruby Laser System
Regulatory Class: II
Product Code: GEX
Dated: June 3, 1997
Received: June 4, 1997

Dear Mr. Hattub:

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.

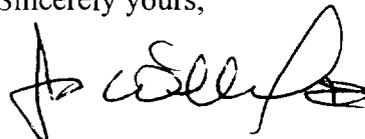
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



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

510(k) Number (If known): K972099

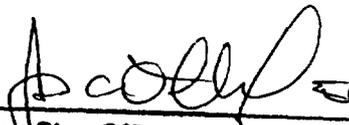
Device Name: Sharplan Ruby Laser System

Indications For Use:

The Sharplan Ruby Laser System, with its fiber delivery system, is intended for use in dermatology for the removal of unwanted body hair.

(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 K972099

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)