



K971648  
JUL 23 1997

510(k) Summary of Safety and Effectiveness  
Sharplan Lasers, Inc. Model 4020 Erbium YAG 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 Model 4020 Erbium YAG Laser System is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which includes the following: SEO Medical Model 2940 Erbium YAG Laser, Candela (Fotona) SkinLight Er:YAG Laser, Con Bio Erbium/2.94 Laser, ESC Derma 20 Erbium:YAG Laser, and Asculap MCL 29 Erbium:YAG Laser.

1. Sharplan Lasers, Inc.  
1 Pearl Court  
Allendale, NJ 07401  
George J. Hattub, Director of Regulatory Affairs/Quality Assurance  
May 2, 1997
2. **Model:** Sharplan Model 4020 Erbium YAG Laser
3. **Predicate Devices:** SEO Medical Model 2940 Erbium YAG Laser (K954013), Candela (Fotona) SkinLight Er:YAG Laser (K962902), Con Bio Erbium/2.94 Laser (K961748), ESC Derma 20 Erbium:YAG Laser (cleared April, 1997), and Asculap MCL 29 Erbium:YAG Laser (K964128).
4. **Description:** The Sharplan Model 4020 Erbium YAG Surgical Laser is a medical device which capable of emitting an invisible pulsed treatment laser beam at a wavelength of 2.94  $\mu$  under the guidance of an visible aiming beam. This laser can be utilized in either the continuous or timed exposure modes of operation
5. The Sharplan Model 4020 Erbium YAG Surgical Laser is intended for incision/excision, ablation, vaporization, and/or coagulation of soft tissue in Plastic Surgery/Dermatology. No new indications were sought in this premarket notification and no clinical data was presented.

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**(continued)**

6. From both 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, Sharplan Lasers, Inc. believes that no significant differences exist. Therefore, the Sharplan Model 4020 Erbium YAG Surgical Laser 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

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

JUL 23 1997

Re: K971648  
Trade Name: Sharplan Model 4020 Erbium YAG Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: May 2, 1997  
Received: May 5, 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.

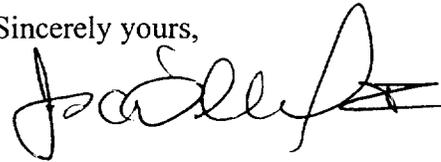
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. George J. Hattub

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,



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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): K97 1648

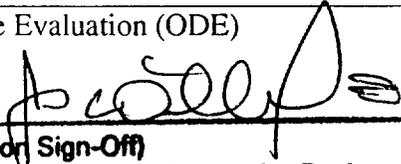
Device Name: Sharplan Model 4020 Erbium:YAG Laser System

Indications For Use:

The Sharplan Model 4020 Erbium:YAG Surgical Laser System is intended for incision/excision, ablation, vaporization, and/or coagulation of soft tissue in Plastic Surgery/Dermatology.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971648

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)