

MAR - 7 1997

K962446

**510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. 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 the Sharplan Lasers, Inc. Ruby Laser System is based on a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Sharplan Ruby Laser, the ThermoLase LT-100 Q-Switched Nd:YAG Laser, the American Hair Removal System, and the Spectrum EpiLaser (Ruby) System.

1. Firm:

Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
December 6, 1996
George J. Hattub, Director of Regulatory Affairs
1-800-394-2000, ext. 531

2. Model:

Sharplan Lasers, Inc. Ruby Laser System (*for Hair Removal Indication*)

3. Predicate Devices:

The Sharplan Ruby Laser, the ThermoLase LT-100 Q-Switched Nd:YAG Laser, the American Hair Removal System, and the Spectrum EpiLaser (Ruby) System.

4. Description:

The Sharplan Ruby Laser System is a surgical laser which is capable of providing pulsed (Q-Switched or Free Running) laser energy of a 694.3 nm wavelength through an articulated arm 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. Intended Use:

The Sharplan Lasers, Inc. Ruby Laser System is substantially equivalent to the following devices: the Sharplan Ruby Laser, the ThermoLase LT-100 Q-Switched Nd:YAG Laser, the American Hair Removal System, and the Spectrum EpiLaser (Ruby) System (K961279, K950019, K892514, and K955612 respectively). It is intended for use in dermatology for the removal of unwanted dark body hair.

Clinical data on 31 patients with a 3 month follow-up period was presented in order to demonstrate the safety and efficacy of the device.

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

6. Intended Use & Technological Characteristics

From a clinical performance and intended use perspective, two of the predicate devices (the ThermoLase LT 100 and the American Hair Removal System) and the candidate device, (the Sharplan Ruby Laser System) produces a similar result which is the removal of unwanted body hair. In terms of functioning characteristics, for one of the predicate devices (the Spectrum EpiLaser), and the Sharplan Ruby Laser System are of the same technology. Furthermore, they have the same operating principle, and their performance characteristics are similar. Sharplan Lasers, Inc. believes that the differences between the aforementioned devices do not raise any issues pertaining to safety or efficacy.

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.

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