

JUN 18 1996

K 961279

**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 Spectrum RD-1200 Ruby Laser and the Derma-Lase DLR Ruby Laser.

**1. Firm:**

Sharplan Lasers, Inc.  
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Allendale, NJ 07401  
April 1, 1996  
George J. Hattub, Director of Regulatory Affairs  
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**2. Model:**

Sharplan Lasers, Inc. Ruby Laser System

**3. Predicate Devices:**

The Spectrum RD-1200 Ruby Laser and the Derma-Lase DLR Ruby Laser

**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 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 Spectrum RD-1200 Ruby Laser and Derma-Lase DLR Ruby Laser, (K910422 and K924647, respectively). It is intended for use in dermatology for photothermolysis, for the specific indications {in adults (18 years or older)} to remove blue-black tattoos, or to remove or lighten benign epidermal pigmented lesions.

No new indications were sought in this premarket notification and no clinical data was presented.

**REVISED JUNE 7, 1996**

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

**6. Technological Characteristics**

From a clinical performance perspective, the aforementioned devices produce a similar therapeutic output in terms of laser wavelength and spot size (5-8mm). Regarding the technological characteristics, while are not identical, physical testing of the device has demonstrated that it is similar both in function and performance to its predicate devices. Sharplan Lasers, Inc. believes that none of the differences of the device raise any issues pertaining to its 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.

**REVISED JUNE 7, 1996**