MAR - 5 1997

K963947

ATTACHMENT I
(Rev. 12/96)

510(K) SUMMARY

Epilaser™ Normal Mode Ruby Laser

This 510(k) Summary of safety and effectiveness for the Epilaser™ Normal Mode Ruby Laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Spectrum Medical Technologies, Inc.
Address:	45 Hartwell Avenue Lexington, MA 02173
Contact Person:	Mr. Sanford Lane President, Spectrum Medical Technologies, Inc.
Telephone:	617-676-7300 617-676-7330 (Fax)
Preparation Date: (of the Revised Summary)	December 26, 1996
Device Trade Name:	Epilaser™ Normal Mode Ruby Laser
Common Name:	Ruby Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (see 21 CFR 878-4810) Product Code: GEX Panel: 79
Legally Marketed Predicate Device(s):	Epilaser™ Normal Mode Ruby Laser (K955612) Thermolase LT-100 Nd:YAG Laser (K950019)
Description of the Device:	The Epilaser™ Normal Mode Ruby Laser operates at 694.3 nanometers with pulse durations of 0.2 - 3.0 msec. The energy is delivered to the treatment site by an articulated arm. A water-cooled handpiece (7 mm or 10 mm) is firmly held against the skin for 2-3 seconds and the laser is then fired.

The Epilaser™ Normal Mode Ruby Laser is capable of producing energy fluences of 10-75 J/cm^2.

Intended Use:

The Epilaser™ Normal Mode Ruby Laser is intended to effect hair removal of patients with skin types 1 - 4 through selective photothermolysis of hair follicles in dermatology and plastic surgery. This results in a prolonged growth delay.

Comparison:

The Epilaser™ Normal Mode Ruby Laser for hair removal has the same technological characteristics as the predicate Epilaser (K955612). It differs from the Thermolase LT-100 Nd:YAG Laser predicate device (K950019) in that the Thermolase applies laser energy at 1064 nanometers in 10 nsec pulses onto a cream containing carbon. The devices operate by selective photothermolysis.

Performance Data:

Animal and clinical studies were conducted to provide assurance that differences in the specifications of the Epilaser™ Normal Mode Ruby Laser and the claimed predicate device for hair removal did not result in different performance during use.

Animal Studies:

Biopsies of control skin showed no alterations the follicular epithelium or dermal collagen. Examination of irradiated skin showed damage to the follicular epithelium. Focal collagen damage in reticular dermas occurred immediately adjacent to the hair follicle.

Observed effects increased with fluence levels.

Clinical Studies:

Observations in an initial study were recorded prior to treatment and at 1, 3, and 6-months after treatment. There was no scarring in any subject.

The initial study demonstrated that selective photothermolysis targeting melanin in the human hair follicle is an effective tool for hair removal, resulting in a prolonged growth delay.

Subsequent studies, including patients treated for facial hair, confirmed the results of the initial study.

CONCLUSION:

Based on the foregoing, the Epilaser™ Normal Mode Ruby Laser is substantially equivalent to legally marketed claimed predicate devices, i.e., the Epilaser™ for dermatology and plastic surgery and the Thermolase LT-100 Nd:YAG laser for hair removal.