

APR 11 1997

510(K) PREMARKET NOTIFICATION
Derma™ 20 Laser System
ESC Medical Systems Ltd.
Revised March 12, 1997

K964253

510(K) Summary

Submitter: ESC Medical Systems Ltd.
Yokneam Industrial Park
Yokneam, 20692, Israel
Phone: 972-4-959-9000 Fax: 972-4-959-9050

Contact: Dr. Zvi Ladin, VP, Clinical Applications and Regulatory Affairs

Date summary prepared: March 12, 1997

Device Trade Name: Derma™ 20 Laser System

Common name: Erbium:YAG laser system

Classification name: Laser instrument, powered, surgical (class II medical device)

Equivalent Devices: SEO Trilase 2940 Erbium Laser (K954013)
Fotona Skinlight Laser System (K962902)
Continuum Biomedical Medlite/Erbium Laser System (K961748)

Device Description: Derma™ 20 is a pulsed medical laser system incorporating an Er:YAG laser, operating at a wavelength of 2.94 microns. The device emits pulses of up to 1.7 joules on tissue. The pulse width is 350 µsec, the pulse rate is 5-12 pulses per second.
The system is composed of the following units:

- Laser optical rail assembly
- Articulated arm
- Power supply and pulse forming network (PFN)
- Cooling system
- Control electronics system
- Power distribution box

Intended Use: Incision, excision, ablation, vaporization and hemostasis of soft tissue

Comparison: The Trilase 2940 Erbium Laser, the Medlite\Erbium Laser System and the Fotona Skinlight System are all Erbium:YAG lasers with pulse energy of up to 2 Joules and pulse rates 2-20 Hz. The Derma™ 20 Laser System characteristics are within the range of these values.

Nonclinical Performance Data None

Clinical Performance Data None

Conclusion The Derma™ 20 Laser System is substantially equivalent to other Erbium:YAG laser systems in commercial distribution for similar surgical applications

Additional Information None requested at this time