

k980361

APR 21 1998

510(k) SUMMARY

DERMABLATE ERBIUM LASER SYSTEM

This 510(k) summary of safety and effectiveness for the Dermablade erbium laser system 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: AESCULAP-MEDITEC

Address: 23832 Via Monte
Coto De Caza, CA 92679-4001

Contact Person: Mr. William T. Kelley
AESCULAP-MEDITEC
23832 Via Monte
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Telephone: 714-589-8536
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Preparation Date: January 1998
(of the Summary)

Device Trade Name: Dermablade Er:YAG Laser System

Common Name: Erbium: Yttrium, Aluminum; Garnet (Er:YAG) Laser System

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810). Product Code: GEX.

Legally marketed predicate(s): MCL 29 Dermablade Continuum Biomed, Inc., Multilite Erbium Laser System

Description of the device: The Dermablade laser is an erbium:YAG laser operating at 2.94 microns and with a maximum pulse energy of 2 J.

Intended Use: The Dermablade laser is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

This intended use is the same or similar to that for the claimed predicate devices.

Performance Data: None. The specifications and intended uses of the Dermablade laser are the same or very similar to those of the claimed predicate devices, including the MCL 29 Dermablade. There are no significant differences between the devices under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing and other information in this application, AESCULAP-MEDITEC believes that the Dermablade laser is substantially equivalent to legally marketed predicate devices, i.e., the MCL 29 Dermablade and the Continuum Biomed, Inc. Multilite erbium laser system (K961748 and K970934).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

Mr. William T. Kelly
Aesculap-Meditec North America
23832 Via Monte
Coto De Caza, California 92679

Re: K980361
Trade Name: Dermablate Er:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: January 27, 1998
Received: January 29, 1998

Dear Mr. Kelly:

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.

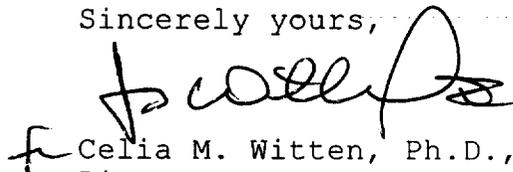
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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): K980361

Device Name: Dermablate Erbium Laser System

Indications For Use:

The Dermablate laser is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 810.109)

OR Over-The-Counter-Use _____

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980361