K992707

OCT 19 1999

510(k) SUMMARY
AESCULAP-MEDITEC GMBH
DERMABLATE ER:YAG LASER SYSTEM

This 510(k) summary of safety and effectiveness for the AESCULAP-MEDITEC GMBH DERMABLATE ER:YAG LASER SYSTEM is submitted in accordance with the requirements of SDMA 1990 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant: AESCULAP-MEDITEC GMBH

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Contact Person: Dr. Dirk Colditz
Quality Management Representative

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Preparation date: July 25th, 1999

Device name: DERMABLATE ER:YAG LASER SYSTEM

Common Name: DERMABLATE ER:YAG LASER SYSTEM

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product code: GEX – Laser instrument, surgical, powered
Panel: SU

Legally marketed: Sharplan Silktouch CO2 Flash Scanner, Coherent Ultrapulse CO2 Surgical Lasers, Ultrapulse S Series CO2 Surgical Lasers

Description: The laser system DERMABLATE ER:YAG LASER SYSTEM is an Erbium:YAG laser with a wavelength of 2.94µm.

Intended Use: The laser system DERMABLATE ER:YAG LASER SYSTEM is intended for laser assisted site preparation for hair transplantation. All other intended uses are part of 510(k) submission No. K980361 and are note changed or affected by this indication for use.

Comparison to: The specifications of the laser system DERMABLATE ER:YAG LASER SYSTEM are the same as or very similar to those of legally marketed lasers such as Sharplan Silktouch CO2 Flash Scanner, Coherent Ultrapulse CO2 Surgical Lasers, Ultrapulse S Series CO2 Surgical Lasers.

Performance data: None. The specifications and intended uses of the laser system DERMABLATE ER:YAG LASER SYSTEM are the same or very similar to those of claimed predicate devices.

Because that, performance data were not required.

CONCLUSION: The DERMABLATE ER:YAG LASER SYSTEM used for laser assisted side preparation for hair transplantation is substantially equivalent to legally marketed devices, e.g. Sharplan Silktouch CO2 Flash Scanner, Coherent Ultrapulse CO2 Surgical Lasers, Ultrapulse S Series CO2 Surgical Lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 1999

Aesculap-Meditec North America
c/o Mr. William Kelley
2525 McGaw Avenue
Irvine, California 92623-9791

Re: K992707
Trade Name: Dermablate Er:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: July 25, 1999
Received: August 11, 1999

Dear Mr. Kelley:

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 (Premarket 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.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K992707

Device Name: *DERMABLATE ER:YAG LASER SYSTEM*

Indication For USE Statement:

The laser system DERMABLATE ER:YAG LASER SYSTEM is intended for laser assisted site preparation for hair transplantation. This indication is in addition to previously cleared indications.

The laser system DERMABLATE ER:YAG LASER SYSTEM is restricted to sale to or use by licensed professionals in the United States.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992707