JUN - 1 2000

K994116

510(k) SUMMARY
AESCULAP-MEDITEC GMBH
LASER SYSTEM MeDioStar H
WITH AND WITHOUT COOLING SYSTEM FOR SKIN

This 510(k) summary of safety and effectiveness for the AESCULAP-MEDITEC GMBH Laser System MeDioStar H with and without skin cooling 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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Preparation date: March 1999

Device name: Laser System MeDioStar H (with and without skin cooling system)

Common Name: MeDioStar H (without skin cooling system)
MeDioStar HC (with skin cooling 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: 79

Legally marketed: Coherent / Palomar - LightSheer (K982940)
LASERSCOPE - Lyra (K990903)
Candela - CANDELA GENTLELASE II DERMATOLOGICAL LASER (K984601)

Description: The laser system MeDioStar H operates as a pulsed diode laser which emits a beam of coherent light at 808 nanometers.

Intended Use: The laser system MeDioStar H is intended to remove unwanted body hair and vascular lesions.

Comparison to: The specifications of the MeDioStar are the same as or

very similar to those of legally marketed lasers such as the Coherent / Palomar - LightSheer (K982940), the LASERSCOPE - Lyra (K990903) and the Candela - CANDELA GENTLELASE II DERMATOLOGICAL LASER (K984601)

Performance data: None. The specifications and intended uses of the laser system MeDioStar H are the same or very similar to those of claimed predicate devices.
Because of this , performance data were not required.

CONCLUSION: The MeDioStar H is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2000

Mr. William Kelley
Aesculap-Meditec North American
2525 McGaw Avenue
Irvine, California 92623

Re: K994116
Trade Name: Laser System MeDioStar H With and Without Skin Cooling System
Laser System MeDioStar With and Without Skin Cooling System
Regulatory Class: II
Product Code: GEX
Dated: February 21, 2000
Received: March 7, 2000

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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K994116

Device Name: *Laser System MeDioStar H with and without skin cooling system*

Indication For USE Statement:

The laser system MeDioStar H (with and without skin cooling system) is intended to remove unwanted body hair and vascular lesions.

The laser system MeDioStar H 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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Donna R. Vochman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994116