K983215

DEC 4 1998

APPENDIX E

510(k) SUMMARY
AESCULAP-MEDITEC
MULTIPULSE CO_2 LASER

This 510(k) summary of safety and effectiveness for the MultiPulse CO_2 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: Aesculap-Meditec

Address: 2525 McGaw Avenue
Irvine, CA 92623-9791

Manufacturer: Aesculap-Meditec GmbH
Prussingstrasse 41
D-07745 Jena
Germany
(011) +49/3641/653223
(011) +49/3641/652121

Contact Person: Mr. William T. Kelley

Telephone: 949-660-2770
949-660-2760 (Fax)

Preparation Date: (of the Summary) September 1998

Device Name: MultiPulse CO_2 laser

Common Name: CO_2 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: Medical Laser Technology, Inc. M.L.T. 30

Device description: The Aesculap-Meditec MultiPulse CO_2 laser emits a beam of coherent light at 10.6 microns.

Indications for use: The Aesculap-Meditec CO_2 Laser is intended for the ablation, vaporization, incision, excision, or cutting of soft tissue in oral surgery, E.N.T., gynecology, and dermatology.

Comparison to predicate device: The specifications of and indications for the Aesculap-Meditec MultiPulse CO_2 laser are the same as or very similar to those of the claimed predicate, the M.L.T. 30 marketed by Medical Laser Technology, Inc.

Performance Data: None. The specifications and indications for use of the Aesculap-Meditec MultiPulse CO_2 laser are the same or very similar to those of the claimed predicate device.

Because of this, performance data were not required.

CONCLUSION: Based on the similarities of specifications and indications for use, Aesculap-Meditec believes that the MultiPulse CO_2 laser described in this notification is substantially equivalent to the cited legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Mr. William T. Kelley
General Manager
Aesculap-Meditec
2525 McGaw Avenue
Irvine, California 92623-9791

Re: K983215
Trade Name: Multipulse CO_2 Laser
Regulatory Class: II
Product Code: GEX
Dated: September 9, 1998
Received: September 14, 1998

Dear Mr. Kelley:

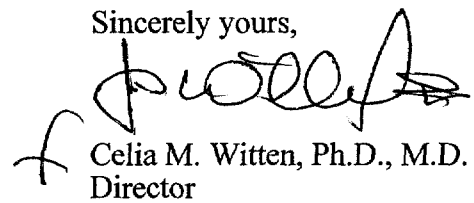
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

APPENDIX B
rev. 10/98

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K983215
Device Name: Aesculap-Meditec MultiPulse CO_2 laser

Indications For Use Statement:

The Aesculap-Meditec CO_2 laser is intended for the ablation, vaporization, incision, excision, and or cutting of soft tissue in:

Oral surgery
Dermatology
Examples: Removal of small skin tumors, superficial pigmented lesions, adeno-sebaceous hypertrophy, treatment of scars, skin tags, etc.
Skin resurfacing (scanning mode)
Blepharoplasty
E.N.T.
Examples: Tumor surgery of the larynx and pharynx
LAUP
Stenosis

CAUTION: Patients should be diagnosed with tissue problems to exclude those whose problems are caused by being overweight or to drinking problems.

Remind patients that there may be vocalization problems after laser surgery.

Gynaecology

The examples are not intended to be exhaustive or complete but to serve as a general guide to the surgeon.

Aesculap-Meditec proposes that the MultiPulse CO_2 laser be limited to prescription use. This labeling will be included in the final printing of the manual and on literature relating to the device.

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

~~Concurrence of CDRH, Office of Device Evaluation (OFFICE OF DEVICE EVALUATION)~~

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983215