

NOV 17 1999

K 991993

APPENDIX F
Rev. Oct. 1999

510(k) SUMMARY
AESCULAP-MEDITEC
PHACOLASE™ ER:YAG LASER

This 510(k) summary of safety and effectiveness for the Phacolase™ Er:YAG 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
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Contact Person: Mr. William T. Kelley

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

Preparation Date: November 1999
(of the Summary)

Device Name: Phacolase™ Er:YAG laser

Common Name: Er:YAG 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

Description: The Aesculap-Meditec Phacolase™ Er:YAG laser emits a beam of coherent light at 2.94 microns.

Indications: The Aesculap-Meditec Phacolase™ Er:YAG laser is intended for cutting, incision, excision, vaporization, and ablation of soft tissue in ophthalmology:

Anterior capsulotomy

Soft tissue surrounding the orbit of the eye

Aesculap-Meditec proposes that the Phacolase™ Er:YAG laser be labeled:
“CAUTION: Federal (US) law restricts the use of this device to licensed professionals.”

Comparisons The Aesculap-Meditec Phacolase™ Er:YAG laser was compared to predicate lasers with the cited indications.

Performance Data: The results of a preclinical and clinical testing were submitted in support of the claim for incision and fragmentation of cataractous lenses during cataract surgery.

CONCLUSION: Based on the preclinical and clinical testing and on comparisons of specifications and other descriptive information the Aesculap-Meditec Phacolase™ Er:YAG laser is substantially equivalent for its claimed indications for use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991993
Trade Name: Phacolase™ Er:YAG
Regulatory Class: II
Product Code: GEX
Dated: September 13, 1999
Received: September 21, 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.

Page 2 – Mr. William T. Kelley

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,

for 

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B2
Rev. Nov. 1999

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): ~~5015258639~~ K 991993

Device Name: Aesculap-Meditec Phacolase™ Er:YAG laser

Indications For Use Statement:

The Aesculap-Meditec Phacolase™ Er:YAG laser is intended for cutting, incision, excision, vaporization, and ablation of soft tissue in ophthalmology:

- Anterior capsulotomy
- Soft tissue surrounding the orbit of the eye

Aesculap-Meditec proposes that the Phacolase™ Er:YAG laser be labeled: "CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

This labeling will be included in the final printing of the manuals 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 (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

John Phuels

(Division Sign-Off)
Division of General Restorative Devices

510(K) Number K991993