K981196

JUN 17 1998

APPENDIX D

510(k) SUMMARY

MEDITEC LINK

This 510(k) summary of safety and effectiveness for the Meditec Link is submitted in accordance with the requirements of SMDA 1990 and follows guidance from the Office of Device Evaluation concerning the organization and content of a 510(k) summary.

Applicant:	Aesculap-Meditec, North America
Address (Manufacturer):	Aesculap-Meditec GmbH Prussingstrasse 41 D-07739 Jena GERMANY
Contact Person:	Mr. William T. Kelley General Manager Aesculap-Meditec, North America 23832 Via Monte Coto De Caza, CA 92679-4001
Telephone:	714-589-8536 714-589-6259 (Fax)
Preparation Date:	March 1998
Device Trade Name:	Meditec Link
Common Name:	Adapter for attachment to slit lamps
Classification Name:	Accessory to an ophthalmic laser (21 CFR 886.4390) Product Code: HJO As an accessory to an ophthalmic laser the device could reference the classification regulation for ophthalmic lasers (21 CFR 886.4390) and the ophthalmic laser product code (HQF).
Class:	An accessory to a medical device is normally placed in the same class as the device to which it is an accessory.
Legally marketed predicate devices:	Infinitech Multi-Spot Slit Lamp laser Adapter

Description of Devices: The Meditec Link is an adapter which attaches to slit lamps, e.g., Zeiss Slit Lamps and Haag Streit 900 BQ and 900 BM Slit Lamps, to allow green laser light, to be delivered to the slit lamps. The laser light (532 nm) can then be directed to selected sites within the eye by an ophthalmologist.

Intended Use: The Meditec Link is intended to be attached to slit lamps to allow green laser energy light to be delivered to the slit lamp via fiber optic.

Once the Meditec Link is attached to a slit lamp the user should refer to the User's Manual or Operator's Manual provided with the laser for clinical use information regarding the laser and for additional use instructions or information.

The Meditec Link is presently designed for attachment to Zeiss Slit Lamps or to Haag Streit 900 BQ and 900 BM Slit Lamps.

Performance Data: The specifications and intended uses of the Meditec Link are the same or very similar to those of the claimed predicate devices. There are no significant differences between the Meditec Link in design or intended use and the claimed predicates under conditions of intended use of these accessories to ophthalmic lasers..

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing, Aesculap-Meditec believes that the Meditec Link is substantially equivalent to legally marketed predicate devices (adapters for slit lamps to allow the introduction of laser light to the slit lamp).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1998

Mr. William T. Kelley
General Manager
Aesculap-Meditec, North America
23832 Via Monte
Coto De Caza, California 92679-4001

Re: K981196
Trade Name: Meditec Link
Regulatory Class: II
Product Code: HQF
Dated: March 17, 1998
Received: March 19, 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

K981196
~~K981186~~

APPENDIX B

510(K) Number (if known): New Submission

Device Name Meditec Link

Indications For Use:

The Meditec Link is intended to be attached to slit lamps to allow green laser energy light to be delivered to the slit lamp via fiber optic.

Once the Meditec Link is attached to a slit lamp the user should refer to the User's Manual or Operator's Manual provided with the laser for clinical use information regarding the laser and for additional use instructions or information.

The Meditec Link is presently designed for attachment to Zeiss Slit Lamps or to Haag Streit 900 BQ and 900 BM Slit Lamps.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981196