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APPENDIX E

510(k) SUMMARY

FEB 19 1998

SL07 and SL08 LASER SLIT LAMPS

This 510(k) summary of safety and effectiveness for the SL07 and SL08 laser slit lamps 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: November 1997

Device Trade Name: SL07 and SL08 Laser Slit Lamps

Common Name: Slit Lamp

Classification Name: Biomicroscope, Slit Lamp, AC powered
(see: 21 CFR 886.1850)
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: Class II medical device (as slit lamps or as accessories to ophthalmic lasers)

Legally marketed predicate devices:

Zeiss and Haag Streit Slit Lamps; Infnitech Multi-Spot Slit Lamp laser Adapter for Haag Streit Slit Lamp; Oculight SLx

Description of Devices:

The SL07 and SL08 slit lamps are commercially available slit lamps which have been modified by Aesculap-Meditec to accommodate an adapter through which green laser light, e.g., from the EyeLite™ Laser, is 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 SL07 and SL08 slit lamps are intended for use in ophthalmology to deliver a thin, intense beam of light into the eye. Both include an adapter to deliver green laser light (532 nm) to the slit lamp by fiber optic. The user should refer to the User Manual provided with the laser for clinical use information for the laser or for additional information

This intended use is the same or similar to that for the claimed predicate devices (see below) and for slit lamps as described in 21 CFR 886.1850, i.e., to direct a thin, intense light into the eye.

Performance Data: The specifications and intended uses of the SL07 and SL08 laser slit lamps are the same or very similar to those of the claimed predicate devices and other legally marketed slit lamps (as devices or as accessories to ophthalmic lasers). There are no significant differences between the SL07 and SL08 devices and claimed predicates under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION:

Based on the foregoing, Aesculap-Meditec believes that the SL07 and SL08 laser slit lamps are substantially equivalent to legally marketed predicate devices.

COMPARISON TABLE/PREDICATE DEVICES

DEVICE CHARACTERISTIC	SL08 SLIT LAMP	SL07 SLIT LAMP	INFINTTECH MULTI-SPOT ADAPTER	ACLON FREQUENCY DOUBLE YAG (Fx-2)
Device	Zeiss SL 20 slit lamp modified to accommodate the adapter	Haag-Streit HS 900 BQ slit lamp modified to accommodate the adapter		Cites Zeiss, Haag-Streit and similar slit lamps
Indications (biomicroscope, slit lamp)	See 21 CFR 886.1850 and medical practice	See 21 CFR 886.1850 and medical practice	No information	Labeled for ophthalmic use; refers to several slit lamps
Spot Size	Range: 50 um - 1000 um Imaging: 50 um - 400 um focusing >400 um - 1000 um defocusing	Range: 50 um - 1000 um Imaging: 50 um - 400 um focusing >400 um - 1000 um defocusing	relies on slit lamp, multi-spot is capable of creating 4 spots centered on guide beam	relies on slit lamps
Laser Connection	50 um fiber with SMA connector	50 um fiber with SMA connector	--	Has connector
Wavelength	Frequency doubled Nd:YAG	Frequency doubled Nd:YAG	Argon/Krpton and frequency doubled Nd:YAG	Frequency doubled Nd:YAG
Eye Protection	For wavelength; protection type L5 (DIN EN 207) at 532 um	For wavelength; protection type L5 (DIN EN 207) at 532 um	not specified; presumably for wavelength	not specified; presumably for wavelength
Tissue Effect of Laser	Photocoagulation	Photocoagulation	Photocoagulation	Photocoagulation
Laser Intensity	selected by physician	selected by physician	selected by physician	selected by physician

Note: The IRIS Oculite Slx brochure (referenced above but not included in the tabular comparisons) cites adapters for the Zeiss 20 SL and Haag-Streit 900 BQ slit lamp.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

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

Re: K974467
Trade Name: AESCULAP- MEDITEC SLIT LAMPS SL07 AND SL08
Regulatory Class: II
Product Code: 86 HJO
Dated: November 21, 1997
Received: November 26, 1997

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.

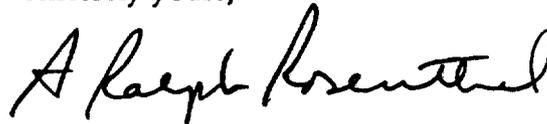
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4613. Additionally, for questions on the promotion and advertising of your devices, 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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K 9 74467

Device Name: SL07 and SL08 Laser Slit Lamps

Indications For Use:

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Daryl L. Kaufman
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 9 74467

(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