FEB 1 1999

AESCULAP

K984124

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Aesculap Xenon Light Source

November 17, 1998

Submitted by: Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Mary Ellen Holden
Phone: (650) 624-5072
FAX: (650) 589-3007

Product: Aesculap Xenon Light Source
Common Name: Xenon Light Source

Intended Use

Aesculap's Xenon Light Source is intended for use as a high intensity light to be used with Fiberoptic cables. Applications include endoscopes, surgical headlamps, and other lighted tools that contain fiberoptic bundles. Illumination from this device is intended to be used for observation of body cavities, hollow organs and other surgical sites. Specific areas of application include arthroscopy, laparoscopy, gynecology, broncoscopy, urology, neuroendoscopy and vascular endoscopy.

Device Description

The Xenon Light Source consists of a light source control unit and fiber optic cables. Technological characteristics are provided below:

Design:	Light Source in stainless steel / aluminum housing
Dimensions:	305mm x 305mm x 82mm
Weight:	6.5kg
Lamp:	180W Xenon
Circuit:	Transistorized
Voltage:	100 - 240V
AC Power Freq.:	50 - 60 HZ

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's Xenon Light Source complies with the following standards which appear on the FDA List of Recognized Consensus Standards:

IEC 60601-1	International Electrotechnical Commission; Medical Electrical Equipment, Part 1: General Requirements for Safety.
IEC 60601-1-2	International Electrotechnical Commission; Medical Electrical Equipment, General Requirements for Safety: Electromagnetic Compatibility - Requirements and Tests.

In addition, the Xenon Light Source meets the requirements of the following Underwriters Laboratories standard.

UL 2601-1	Underwriters laboratories; medical electrical equipment, general requirements for safety.

Sterilization

The Xenon Light Source control unit is not intended for use in the sterile field. The Fiber Optic Cable provided with the Xenon Light Source is provided non-sterile and must be sterilized prior to use. The cable may be sterilized by steam sterilization.

Substantial Equivalence

Aesculap's Xenon Light Source shares similar features and function with corresponding devices distributed by:

EG&G Electro-Optics (K980044)
Lutex (K890716)
Karl Storz (K934559)
Wolf (K952696)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

Ms. Mary Ellen Holden
Senior Regulatory Associate
Aesculap, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7028

Re: K984124
Trade Name: Aesculap Xenon Light Source
Regulatory Class: II
Product Code: FSS
Dated: November 17, 1998
Received: November 18, 1998

Dear Ms. Holden:

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,

for 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

INDICATION FOR USE STATEMENT

K984124

510(k) Number (if known): N/A

Device Name:

Aesculap Xenon Light Source

Indication for Use:

Aesculap's Xenon Light Source is intended for use as a high intensity light to be used with Fiberoptic cables. Applications include endoscopes, surgical headlamps, and other lighted tools that contain fiberoptic bundles. Illumination from this device is intended to be used for observation of body cavities, hollow organs and other surgical sites. Specific areas of application include arthroscopy, laparoscopy, gynecology, broncoscopy, urology, neuroendoscopy and vascular endoscopy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(D...

...ative Devices K984124

510(k) Number

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