APR 3 1998

K980044

13.0 510(k) Summary of Safety and Effectiveness:

December 22, 1997

1. **Device Submitted:** Xenon Light Source

2. **Proprietary Name:** ***Xenon 300mx***

3. **Common Usual Name:**
Xenon Fiber optic Light Source for Medical Procedures

4. **Predicate Device:**
Xenon 300mx manufactured and marketed by EG&G Optoelectronics Division is substantially equivalent to the Karl Storz Cold Light Fountain Xenon 300 manufactured by Karl Storz Endoscopy-America, Inc., Culver City, CA , the Maxenon, manufactured by BFW, Lexington KY and the Brite Lite III manufactured by Applied Fiberoptics Sturbridge, MA.

5. **Device Description:**
EG&G Optoelectronics has engineered the ***Xenon 300mx*** to provide a high intensity white light source for fiber optic cables. The system consists of a single cabinet containing a power supply, a Xenon Lamp with focusing optics, a variable light attenuator, a selector for four standard fiber optic cable sizes, and a forced air cooling system.

6. **Intended Use:**
The EG&G ***Xenon 300mx*** is intended to be used with fiber optic cables for endoscopes, surgical headlamps and other lighted tools that contain fiber optic bundles. Illumination from this device is to be used for observation of body cavities, hollow organs and other surgical sites. Specific areas of application include arthroscopy, laproscopy, gynecology, borncoscopy, urology and vascular endoscopy. The device is also intended for use as a light source for surgical headlights used in various surgical procedures.

7. **Technological characteristic Similarities:**
The EG&G ***Xenon 300mx*** is similar in intended use, design and function to the Karl Storz Xenon 300, BFW MID 3000 and and Applied Fiberoptics Brite Lite III.

8. **Performance Data:**
No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). However, performance data are given for the lamp and power supply in **Attachment 4.** A data base search has been performed to evaluate any adverse effects of devices which are currently marketed. The results are shown in **Attachment 5**.

9. **Effectiveness :** The EG&G ***Xenon 300mx*** medical illuminator provides up to 800 lumens of white light at the output of a seven foot long, 5.0 mm diameter fiber bundle. This level of light output is sufficient for all presently known endoscopic illumination tasks. The internal forced air cooled turret design in addition to providing greater control over the light delivered to the four different types of fiber bundles, also serves to maintain temperature control of the bundle termination.

14.0 Summary:

EG&G Inc. submits that this system is substantially equivalent to several medical illuminator systems presently on the market, while incorporating certain design improvements. All xenon Fiber optic bundle illuminators generate high intensity white light. All of the equivalent systems cited use 300 watt xenon lamps with provision for front panel control of the light level. In addition, all of the equivalent systems are composed of the same basic collection of sub-systems (EMI filtering, AC to DC Conversion, Current Regulation, Lamp Ignitor, Lamp Module, Light Attenuator, and Fiber Bundle Interface).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 1998

Mr. Anthony Statuto
Manager, Quality Assurance
EG&G Electro-Optics
35 Congress Street
Salem, Massachusetts 01970

Re: K980044
Trade Name: Xenon 300mx
Regulatory Class: II
Product Code: FSS
Dated: December 22, 1997
Received: January 6, 1998

Dear Mr. Statuto:

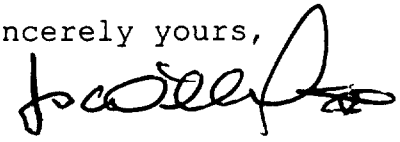
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Attachment #6

510(k) NUMBER (IF KNOWN): K980044

DEVICE NAME: XENON 300 MX

INDICATIONS FOR USE:

The ***Xenon 300mx*** Illuminator 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 contained 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, laproscopy, gynecology, broncoscopy, urology, and vascular endoscopy. The device is also intended for use as a light source for surgical headlights used in various open surgical procedures. These indications are identical to those listed in the Cogent 510(k) number K971057.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980044