K022384 1/1

13.0 510(k) Summary of Safety and Effectiveness

July 18, 2002

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1.	**Device Submitted:**	Xenon Light Source
2.	**Proprietary Name:**	**1300 XSBP – 300 Watt Xenon**
3.	**Common Usual Name:**	Xenon Fiber Optic Light Source for Medical Procedures
4.	**Predicate Device:**	The **1300 XSBP – 300 Watt Xenon** manufactured and marketed by Isolux America is substantially equivalent to the Karl Storz Cold Light Fountain Xenon 300 manufactured by Karl Storz Endoscopy-America, Inc., Culver City, CA. Also the Maxenon, manufactured by BFW, Lexington KY and Brite Lite III manufactured by Applied Fiberoptics, Sturbridge, MA.
5.	**Device Description:**	Isolux America has engineered the **1300 XSBP – 300 Watt Xenon** 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 attenuator, a turret selector for four standard fiber optic cable connectors and a forced air cooling system consisting of two fans.
6.	**Intended Use:**	The Isolux America **1300 XSBP – 300 Watt Xenon** is intended to be used with fiber optic cables for endoscopes, surgical headlamps and other tools that contain fiberoptic 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, broncoscopy, 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 Isolux America **1300 XSBP – 300 Watt Xenon** is similar in use, design and function to the Karl Storz Xenon 300 BFW MID 3000 and the 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 Isolux America **1300 XSBP – 300 Watt Xenon** medical illuminator provides up to 600,000 Lux of white light at the output of an eight 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 bundle connectors, also serves to maintain temperature control of the bundle termination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2002

Isolux America
Nikolaos Andreoulakis
Quality Control Manager
1479 Rail Head Boulevard
Naples, Florida 34110-8444

Re: K022384
Trade/Device Name: Xenon Fiberoptic Light Source, Model 1300 XSBP
Regulation Number: 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: Class II
Product Code: HIE
Dated: July 18, 2002
Received: July 22, 2002

Dear Mr. Andreoulakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K022384

DEVICE NAME : 1300 XSBP – 300 WATT XENON

INDICATIONS FOR USE :

The **1300 XSBP – 300 WATT XENON** Illuminator is intended for use as a high intensity light to be used with fiberoptic cables. Applications include endoscopes, surgical headlights and other 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, 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.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use____
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022384