SEP 14 1999

K992050

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Summary of Safety and Effectiveness

Submitter Name and Address: Walter Lorenz Surgical, Inc
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Contact Person and Telephone Trevor Byrd
(904) 741-9455

Device Name: Lumenon™ Xenon Light Source

Classification Name and Reference: Light Source, Endoscope, Xenon Arc

Intended Use: The Lumenon™ Xenon Light Source is intended to supply adjustable high intensity illumination for accessories such as headlights and endoscopes.

Detailed Device Description: The Lumenon™ Xenon Light Source is a fiberoptic illuminator for supplying high intensity illumination for accessories such as headlights and endoscopes. The device has a universal turret with four (4) receptacles to accept various light cables. It features a quick-change lamp module and two (2) lamp life indicators. The device incorporates a graduated shutter to attenuate the intensity of the light output, adjustable from 0 to 100 percent. The intensity control is adjusted by turning the attenuater knob located on the front panel
The Lumenon™ Light Source utilizes a Plano Convex Lens for focusing light down to the diameter of the fiber optic cable. The 5600°K, light is produced by a Xenon Ceramic Short Arc Lamp. The visible output is 515 X 10(3) Candelas. The equivalent visible output in terms of Lux is 47,862 Lux. ORC coats the glass window of the xenon lamp in order to reduce UV output. The IR is reduced by a glass filter with an IR coating which blocks IR transmissions. UV output is 2.6 watts.

Potential Risks:

- The Lumenon™ Xenon Light Source must not be used in the presence of flammable anesthetics or other flammable gases due to the danger of possible explosion.
- High energy radiated light guided through endoscopes or fiber optics may produce high temperatures in front of the light outlet and at the tip of the instrument.
- Verify that the tip of the instrument is not in excess of 41° C prior to use.
- This product should be used only with type BF endoscopic instruments which have been certified according to IEC 601-1 for medical equipment and IEC 601-2-18 for endoscopic equipment.
- The lamp produces high intensity visible and ultraviolet radiation that may cause burns to skin or eyes.
- Adequate cooling is required for proper operation of the unit.
- Grounding reliability is achieved only when connected to a "Hospital-use" or "Hospital-grade" receptacle.
- Disconnect the power cord before attempting any service to the Lumenon™ Xenon Light Source
- The lamp is filled with xenon gas at very high pressure. Do not subject the lamp to mechanical forces or rough handling, explosion may result.

Substantially Equivalent Device: The Lumenon™ Xenon Light Source is substantially equivalent to the Welch Allyn Xenon 300 Light Source, the Xenon Light Source Model LS 6035 and other legally marketed Xenon Light Sources in operational principles, and technological characteristics. Any difference between devices are minor and rise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

Mr. Trevor Byrd
Regulatory Assistant
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Re: K992050
Lumenon Xenon Light Source
Dated: August 18, 1999
Received: August 19, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 GCT

Dear Mr. Byrd:

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 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). 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 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.

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992050

Device Name: Lumenon Xenon Light Source

Indications For Use: The Lumenon Xenon Light Source is intended to supply adjustable high intensity illumination for accessories such as headlights and endoscopes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 FR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992050