JUL 24 1998

K981804

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CONTEC MEDICAL/Austin & Associates, Inc.
1109 Sturbridge Road Fallston, Maryland 21047 Phone 410/877-3269/Fax 410/877-0544

510(k) SUMMARY

The enclosed is a Summary of our 510(k) Submission of a Xenon Light Source which is substantially equivalent to many current and legally marketed devices.

TRADE NAME:
Xenon Light Source Model LS 6000

CLASSIFICATION NAME:
Light Source, Endoscope, Xenon Arc

EQUIVALENCE:
The Xenon Light Source Model LS 6000 is substantially equivalent to current and legally marketed devices. Examples are enclosed and include the Richard Wolf Model 5141(K944821), Model 5135 (K944607), the Karl Storz Model 201315-20 (K954561) and the Linvatec Model 8430 (enclosed brochure information).
Each Xenon Light Source is designed the same, meets the same specifications and its indication is the same. The only difference between each model is the Watt of the light source lamp.

DESCRIPTION:
The Model LS 6000 is an electronic light source using a 100Watt Xenon lamp, to provide light for endoscopic procedures.

INTENDED USE:
The Model LS 6000 Xenon Light Source is intended for use in endoscopic applications.

CHARACTERISTICS:
There is no significant technological characteristics of the Model LS 6000 compared to existing, legally marketed devices of which examples are listed (Equivalence Section above). The lamp utilized with the LS 6000 is a 100 Watt lamp.

Summary Prepared by:

Albert Austin
Manager/Sales and Quality Assurance
CONTEC Medical/Austin & Associates,Inc.

Summary Prepared On:

5/20/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 1998

Contec Medical Ltd.
c/o Mr. Albert Austin
Austin & Associates, Inc.
1109 Sturbridge Road
Fallston, MD 21047

Re: K981804
Xenon Light Source
Dated: May 20, 1998
Received: May 21, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 GCT and 78 FCW

Dear Mr. Austin:

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 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,

Lillian Yin, Ph.D.
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):_____

Device Name: Xenon Light Source, Model LS6000

Indications For Use:

The Xenon Light Source Model LS6000 is designed to supply light for endoscopic diagnostic observation and surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981804

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)