

K980281

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FEB 27 1998

"510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn Inc.
4619 Jordan Road, Box 187
Skaneateles Falls, New York 13153-0187

Contact Person & Telephone: Kathy Lowther
(315) 685-2897

Date Summary Prepared: January 19, 1998

Device Name: Classification Name - Endoscope and Accessories
Common/Usual Name - Xenon 300 Light Source
Proprietary Name - Welch Allyn Xenon 300 Light Source

Predicate Device: Luxtec Model 9300 Xenon Light Source (A 510(k) could not be located for this device. However, the following Luxtec 510(k) numbers may be appropriate: K864385, K890716, or K864380. It is assumed Luxtec is utilizing one of the above 510(k) numbers as an equivalent device.)

Device Description, intended Use & Effectiveness:

The purpose of the Welch Allyn 300 Watt Xenon Light Source is to provide lighting for medical applications requiring high intensity illumination. The intended use is to provide illumination for medical products such as existing and approved headlights and various existing and approved rigid or flexible endoscopes. The Welch Allyn 300 Watt Xenon Light Source is effective for its intended use.

Technological Characteristics:

See Attachment "A" for a comparison of the features and specifications of the Welch Allyn 300 Watt Xenon Light Source to the predicate device.

Summary of Safety:

The Welch Allyn 300 Watt Xenon Light Source is designed to provide electrical safety to the patient as well as the user. The system is designed to meet the following standards related to electrical safety: UL 2601, CSA 601-1, and IEC 601-1.

To provide mechanical safety to the user, all contact surfaces shall be rounded, textured, or deburred where possible and if necessary.

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ACGIH TLV's (American Conference of Governmental Industrial Hygienists Threshold Limit Values (1994 - 1995.) Ultraviolet, Light, and Near Infrared Sections) equations will be used as a basis of comparison for the Welch Allyn 300 Watt Light Source and the predicate device in their intended application. The system will also be certified to the following standards:

IEC601-1-2

CE Mark Conforms with provisions of European Council Directive 93/42/EEC concerning medical devices.

Summary of Effectiveness:

The Welch Allyn 300 Watt Xenon Light Source is effective for its intended use of providing illumination for medical products such as existing and approved headlights and various existing and approved rigid or flexible endoscopes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Ms. Kathy Lowther
Quality Engineer
Welch Allyn, Inc.
4619 Jordan Road, Box 187
Skaneateles Falls, New York 13153-0187

Re: K980281
Welch Allyn 300 Watt Xenon Light Source
Dated: January 20, 1998
Received: January 26, 1998
Regulatory Class: II
21 CFR §876.1500/Product Codes: 78 GCT & FCW

Dear Ms. Lowther:

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 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) 594-4613. 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/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

510(k) Number (if known): _____

Device Name: Welch Allyn 300 Watt Xenon Light Source

Indications For Use:

The Welch Allyn 300 Watt Xenon Light Source is indicated for medical lighting applications requiring a remotely located, high intensity illumination. The device is not indicated for neonate transillumination.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Matting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980251

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)