

DEC 11 1998

K 983628

Pg 1 of 2

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Vernon Hills, Illinois 60061
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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION



510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: October 13, 1998	
Company / Institution name: Richard Wolf Medical Instruments Corp.		FDA establishment regulation number: 14 184 79	
Division name (if applicable): N.A.		Phone number (include area code): (847) 913-1113	
Street address: 353 Corporate Woods Parkway		FAX number (include area code): (847) 913-0924	
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: Auto LP 5123 Xenon Light Projector		Model number: 5123.011	
Common name: Xenon Light Source		Classification Name: Xenon Light Source	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name		Manufacturer
1 K952696	1 Xenon Light Source		1 Richard Wolf M.I.C.
2	2		2
3	3		3

1.0 Description

Light Projector AUTO LP 5123 uses a xenon arc lamp to provide illumination for an endoscope via a light guide which is connected to the projector's light port. The illumination level is automatically controlled by video.

K 983628
Pg 2 of 2



2.0 Intended Use

Light Projector AUTO LP 5123 provides light for examination, diagnostic and therapeutic applications, in particular, in endoscopy.

The Xenon Light Source is classified as Cardiac Floating (CF) which permits its use for cardiac procedures when used in conjunction with the proper instrumentation for entry into the cardiac system.

3.0 Technological Characteristics

The color temperature of the 180 W xenon arc lamp is about 5600 K. The service life is approximately 500 hours and will decline with time due to the number of starts. The light projector is a type CF applied part per IEC601-1.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as existing devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf.

5.0 Performance Data

Independent laboratories tested the Xenon Light Source 5123 according to specified standards IEC601-1 amendment 1 and 2, IEC601-1-1, and IEC601-2-18. The certifications for UL and CE compliance are pending.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa
Robert L. Casarsa
Quality Assurance Manager

Date: Oct 12 98



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K983628
Auto LP 5123 Xenon Light Projector
Dated: October 13, 1998
Received: October 15, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 GCT

Dear Mr. Casarsa:

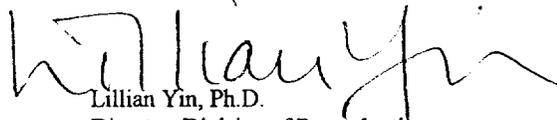
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Indications for Use

510(k) Number (if known): K983628

Device Name: Light Projector AUTO LP 5123

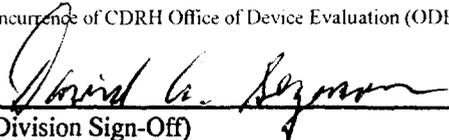
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K983628

Prescription Use ✓
Per 21 CFR 801.109

OR
2 - 1

Over-The Counter _____