K033113
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DEC 2 3 2003

RICHARD WOLF
Medical Instruments Corporation

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12.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **September 29, 2003**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration 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: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: Universal Operating Hysteroscope Set by Solima – Zupi	Model number: 8753.xxx
Common name: Operating Hysteroscopy Set	Classification name: Hysteroscope and Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-amendment	1 Hysteroscopes and Accessories 4998, 8998	1 Richard Wolf
2 K880314/B	2 Hysteroscope Autonom 4995	2 Richard Wolf
3 K000673	3 Hysteroscope Operating Sheaths and Inserts	3 Richard Wolf

1.0 Description

The universal operating hysteroscope set has exchangeable inner sheaths that are inserted into the endoscope containing an angled eyepiece. The endoscope tube consists only of the pure optical system with the light fibers. This allows enough room for various inner sheaths with the operating channel, combined with outer sheaths. The submitted universal hysteroscope set is an inexpensive alternative for compact instruments for outpatient gynecologists.

2.0 Intended Use

The Universal Operating Hysteroscope Set is used for dilating the cervical channel, the cavum uteris (using fluid or CO_2 gas), and for visualization of the tubal ostia. The scope is applied via the natural passage.

3.0 Technological Characteristics

The advantage of the exchangeable inner sheaths is that the same endoscope, which is the part with the highest costs, can be used for various applications with optimized outer diameter, when changing only the inner sheath with the associated outer sheath.
Due to the angled eyepiece, the insertion of the instruments is straight. This implies more user comfort.
A silicate image bundle is used instead of rod lens system to attain a bright picture with a small diameter of optical system. In addition the optical system is more flexible and the risk of rupture of the optical system is reduced.
The various inner sheaths with their associated outer sheaths (color coded) are connected to the endoscope by automatic snap-in locking mechanism, which facilitates the connection of the sheath to the insert. Due to the channel in the inner sheaths, the combination can be used with intermittent irrigation or also with continuous flow irrigation, if they have an additional channel in the outer sheath.
The automatic silicone diaphragm valve at the instrument port allows single-handed operation.

4.0 Substantial Equivalence

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

5.0 Performance Data

No performance standards are known.

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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 instructions manual.

By: Robert L. Casarsa Date: Dec 12, 2003

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Co.
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K033113
Trade/Device Name: Universal Operating Hysteroscope Set by Solima-Zupi
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: September 29, 2003
Received: September 30, 2003

Dear Mr. Casarsa:

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 Indications for Use

510(k) Number (if known): K033113

Device Name: Universal Operating Hysteroscope Set by Solima – Zupi

Intended use: The Universal Operating Hysteroscope Set is used for dilating the cervical channel, the cavum uteris (using fluid or CO_2 gas), and for visualization of the tubal ostia. The scope is applied via the natural passage.

Revised 12/12/03

(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,
and Radiological Devices
510(k) Number K033113

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter _____

(Optional Format 1'2-96)