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RICHARD WOLF
Medical Instruments Corporation

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12.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **May 14, 2004**
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: VEROSCOPE, Optical Veress Cannula and Dilation Tube System	Model number: 8760.xxx, 4760.xxx, 8921.xxx, 8923.xxx
Common name: Needle, pneumoperitoneum, spring loaded and Cannula and trocar, suprapubic	Classification name: Endoscope and Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K962799	1 Set Laparoscopy, Veress Cannula spring loaded, Telescopes	1 Richard Wolf
2 K971420	2 Mini Laparoscopes, Veress Cannula spring loaded, Telescopes	2 Richard Wolf
3 K003417	3 Mini Fiber Laparoscope/ Hysteroscope Sets	3 Richard Wolf
4 K942201	4 Laparoscopy dilation system	4 Richard Wolf
5 not known	5 Optical VERESS Pneumoperitoneum Needle	5 Karl Storz
6 K983925	6 EndoPath Ultra Veress Insufflation Needle	6 Ethicon Endo-Surgery, Inc.
7 K012539	7 VersaStep System	7 U.S. Surgical (Tyco Health)

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1.0 Definition

The 'Veroscope' consists of an outer trocar sleeve with insufflation stopcock, a veress cannula with a sharp tip, a spring loaded protection tube with a transparent blunt tip and an endoscope.

The 'Veroscope' is similar to a spring-loaded, blunt Veress needle that is used for penetrating tissue layers under endoscopic view.

The Standard Dilation System consists of metal dilation sleeves and a guide rod.

The Dilation Tube System 4760 consists of a plastic dilation tube and trocars with sleeves of various dimensions.

2.0 Intended Use

The 'VEROSCOPE' is used percutaneously for penetrating tissue layers under endoscopic control to safely reach a defined body region. It also serves to create a pneumoperitoneum under visual control in the abdomen.

The Dilation Tube System and the Standard Dilation System is used for dilating surgically created passages in body cavities.

The Veroscope and the Dilation Tube Systems are used for diagnosis and therapy in conjunction with endoscopic accessories in various disciplines such as surgery, gynecology and urology.

3.0 Technological Characteristics

With increased tissue resistance, which is the case in particular with boundary layers, for example, fasciae, the transparent tip is pushed back against the force of the spring, the transparent tip springs back and the puncture site can be observed with the endoscope. By pressing the pushbutton on the veress cannula serves to block the spring-back action of the transparent tip.

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-enactment and 510(k)-devices sold by Richard Wolf, Karl Storz, Ethicon, Autosuture/Tyco and other competitors.

5.0 Performance Data

No performance standards are known.

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: May 14, 2004

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 9 2004

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

Re: K041321
Trade/Device Name: VEROSCOPE, Optical Veress Cannula
Regulation Number: 21 CFR 884.1720, 876.1500
Regulation Name: Gynecologic laparoscope and accessories, Endoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ
Dated: May 14, 2004
Received: May 25, 2004

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 (301) 594-4659. 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 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041321

Device Name: VEROSCOPE, Optical Veress Cannula

Indications For Use: The VEROSCOPE is used percutaneously for penetrating the abdominal cavity under endoscopic control to safely reach a defined body region. It therefore also serves to create a pneumoperitoneum under visual control in the abdomen.

The Dilation Tube System and standard Dilation System is used for dilating surgically created passages in body cavities.

Indications and field of use: The Veroscope and dilation tube systems are used for diagnosis and therapy in conjunction with endoscopic accessories in various disciplines such as surgery, gynecology and urology.

Prescription Use __√_____ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 General, Restorative, and Neurological Devices

510(k) Number K041321