



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Richard Wolf Medical Instruments Corp.
Mr. Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, IL 60061-3110

JUL 27 2015

Re: K051276
Trade/Device Name: HySafe Micro Modular Forceps, Punches and Scissors System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCF, FCI, OCZ
Dated (Date on orig SE ltr): October 4, 2005
Received (Date on orig SE ltr): October 6, 2005

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of October 28, 2005.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051276

5.0 Indications for Use

510(k) Number (if known): K051276

Device Name: HySafe Micro Modular Forceps, Punches and Scissors System

Indications For Use: Rigid forceps, punches and scissors serve for endoscopically controlled grasping, manipulating or cutting, and dissection and removal of tissue / organs or foreign bodies and stones through natural or surgically created passages. For investigation, diagnosis and/or therapy with endoscopic accessories in different areas, e.g. surgery, urology and gynecology, performed by adequately trained and qualified medical personnel.

Holding and grasping forceps : For removing residual tissue and foreign bodies, for holding tissue and organs, for stone extraction, and for positioning and removing stents.

Spoon and biopsy forceps: For removing and gripping tissue and tissue samples, and for extracting foreign bodies.

Punch: For removing and separating soft tissue, cartilage, and other non-bony tissue, and for removing tissue.

Scissors: For cutting adhesions, for dissecting, exposing and for separating soft tissue.

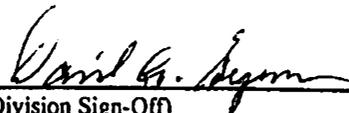
Prescription Use
(Part 21CFR 801 Subpart D)

AND/OR

Over-The Counter Use
(Part 21CFR 801 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 Reproductive, Abdominal,
and Radiological Devices

510(k) Number K051276

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12.0 510(k) Summary of Safety and Effectiveness			
Submitter:		Date of Preparation: May 16, 2005	
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:		Model number:	
Common name:		Classification name:	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K971315	1 Auxiliary Rigid Forceps	1 Richard Wolf	
2 K935270	2 Modular Forceps and Scissors	2 Richard Wolf	

1.0 Description

HySafe Micro Modular Forceps, Punches and Scissors System, consist of a handle and jaw attachment (jaw assembly, various styles/shaped jaws).

2.0 Intended Use

Rigid forceps, scissors and punches serve for endoscopically controlled grasping, manipulating or cutting, and dissection and removal of tissue / organs or foreign bodies and stones through natural or surgically created passages.

For investigation, diagnosis and/or therapy with endoscopic accessories in different areas, e.g. surgery, urology and gynecology, performed by adequately trained and qualified medical personnel.



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Holding and grasping forceps: For removing residual tissue and foreign bodies, for holding tissue and organs, for stone extraction, and for positioning and removing stents.

Spoon and biopsy forceps: For removing and gripping tissue and tissue samples, and for extracting foreign bodies.

Punch: For removing and separating soft tissue, cartilage, and other non-bony tissue, and for removing tissue.

Scissors: For cutting adhesions, for dissecting, exposing and for separating soft tissue.

3.0 Technological Characteristics

The possibility of axial flushing of the insert allows optimal rinsing/ cleaning inside. Due to the overload protection in the handle, the service life is significantly increased and reduces the risk of damage during operation by absorbing excessive force.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices and 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

No performance standards are known. Strength test and ageing measures on forceps with strain relief (spring) show that there is no breakage of the jaw or other parts of the instrument if used normally.

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
Robert L. Casarsa
Quality Assurance Manager

Date: Oct 4, 2005