

JUL 7 1998

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



K981321

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: April 8, 1998	
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			FDA establishment registration number: 1418479	
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: Bipolar forceps set (modular)		Model number: 8390.xxx, 8391.xxx, 8393.xxx, 8394.xxx		
Common name: Modular Bipolar forceps		Classification name: Bipolar forceps		
Information on devices to which substantial equivalence is claimed:				
510(k) Number	Trade or proprietary or model name		Manufacturer	
1 pre-enact.	1 Kleppinger bipolar forceps 8383.21, 8384.21		1 Richard Wolf GmbH	
2	2		2	

1.0 Description

The modular bipolar forcep set provides precise grasping and axial holding placement of the jaws, performs thorough hygiene, and site irrigation can be achieved without using additional instruments.

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**2.0 Intended Use**

The bipolar forceps are used for coagulation of tubes, tissue coagulation, and vascular coagulation to stop bleedings under endoscopic vision.

Not to be used for female sterilization (coagulation of fallopian tubes).

3.0 Technological Characteristics

There are no significant technological characteristic changes to the new devices compared to the pre-enactment devices. The insulation of the electrodes is changed to a more durable coated material. An irrigation port is added.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf. In addition, the submitted devices are substantially equivalent to devices sold by various competitors.

5.0 Performance Data

No known FDA performance standard exists.

The bipolar forceps were tested to meet the appropriate sections of the ANSI/ AAMI standard on high frequency devices HF18 and IEC601-1/ IEC601-2-2. Device materials tests were performed to assure biocompatibility of the new material. The tests indicated that no irrigation would occur.

6.0 Clinical Tests

No special 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
Quality Assurance Manager

Date:

Revised 6/19/98



JUL 7 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert L. Casarsa
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K981321
Trade Name: Modular Bipolar Forceps
Regulatory Class: II
Product Code: GEI
Dated: April 8, 1998
Received: April 10, 1998

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.

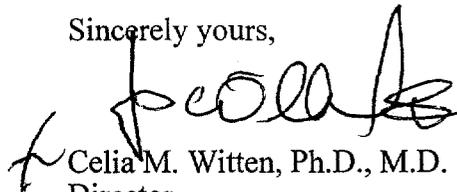
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Robert Casarsa

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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

Enclosure

Indications for Use

510(k) Number (if known): K981321

Device Name: Bipolar Forceps Set (modular)

Intended Use:

For the coagulation of tubes, tissue coagulation and vascular coagulation to stop bleedings under endoscopic vision.

Indication and field of application:

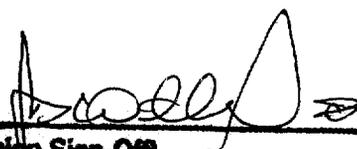
For therapy in connection with endoscopic accessories used in medical specialties such as urology, gynecology, surgery.

Contraindications:

Not to be used for female sterilization (coagulation of fallopian tubes).

Contraindications are inflammations or bacterial contamination of wounds in the operation site. Contraindications directly related to the product are currently unknown. The attending physician must determine if the intended use is appropriate based on the general condition of the patient. For further instructions, refer to the latest medical literature.

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



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981321

Prescription Use
Per 21 CFR 801.109

OR

Over-The Counter

Revised 6/19/98