4/16/99

K990147

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: January 13, 1999
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 forcep set (modular)	Model number: 8393.741, 8393.771, 8394.741, 8394.771
Common name: Modular Bipolar forceps	Classification name: Coagulator-Cutter, Endoscopic, Bipolar Accessories

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 K981321	2 Modular Bipolar Forcep Sets 8390/91/93/94	2 Richard Wolf Medical Instruments

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 coagulation of tubes, tissue coagulation and vascular coagulation, and to stop bleedings under endoscopic vision, including coagulation of the fallopian tube and the mesoalpinx for female sterilization.

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. A cleaning port is added. The instruments are identical to those cleared by K981321.

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 Date: Apr 16, 99

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1999

Mr. Robert L. Casarsa
Quality Assurance Manager
RICHARD WOLF MEDICAL INSTRUMENTS CORP.
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K990147
Modular Bipolar Forcep Set, Kleppinger Principle
Dated: January 13, 1999
Received: January 19, 1999
Regulatory Class: III
21 CFR 884.4150/Procode: 85 HIN

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 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). 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 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K990147

Device Name: Modular Bipolar Forcep Set, Kleppinger Principle

Intended Use:

The coagulation of tubes, tissue coagulation and vascular coagulation, and to stop bleedings under endoscopic vision, including coagulation of the fallopian tube and the mesoalpinx for female sterilization.

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

Prescription Use ✓ OR Over-The Counter ____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990147