K964329

MAY 21 1997

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: October 25, 1996
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: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: Unipolar Electrosurgical Hook Electrode	Model number: 8383.423, 8384.423
Common name: Hook Electrode	Classification name: Electrosurgical cutting and coagulation device and accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enactment	1 Hook Electrode 8383.42	1 Richard Wolf Medical Instruments
2 existing device	2 Hook Electrodes 8383.423, 8384.423	2 Richard Wolf Medical Instruments
3	3	3

1.0 Description

The Hook Electrode is a unipolar electrosurgical device used primarily for cutting, but also usable for coagulation. The device is attached via cable to an electrosurgical generator.

2.0 Intended Use

The electrosurgical unipolar hook electrode is intended to be used for coagulation and cutting of tissue.

3.0 Technological Characteristics

- durable powder coating
- 3000 Volt isolation
- gas and steam sterilizable

4.0 Substantial Equivalence

The basic design of the hook electrode is equivalent to pre enactment devices from R.Wolf and equivalent to existing competitive devices.

5.0 Performance Data

Tested to assure 3000 volt isolation and validation to recommended sterilization processes.

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 instruction manual.

By: Robert J. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: Oct 25, 1996

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1997

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

Re: K964329
Trade Name: Electrosurgical Hook Electrodes
Regulatory Class: II
Product Code: GEI
Dated: April 18, 1997
Received: April 22, 1997

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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,

for 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

510(k) Number (~~if known~~): K 964329

Device Name: ELECTOSURGICAL HOOK ELECTRODES

Indications For Use:

The electrosurgical unipolar hook electrode is used for coagulation and cutting of tissue.

(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 Devices
510(k) Number K964329

PRESCRIPTION USE X OR OVER-THE-COUNTER USE
(PER 21 CFR 801.109)