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K970961
P102

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

APR 10 1998

Summary of Safety and Effectiveness

Submitter:		Date of Preparation: April 6, 1998	
Company / Institution Name: Richard Wolf Medical Instruments Corporation		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: Robert L. Casarsa			
Contact Title: Quality Assurance Manager			

Product Information:			
Trade name:	EVAP Electrodes	Model number:	
Common name:	Roller Electrode Coagulation Electrode Electrosurgical Electrode	Classification name:	Electrode, Electrosurgical

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1.	1. See contents of submission	1.
2.	2.	2.
3.	3.	3.
4.	4.	4.
5.	5.	5.

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1.0 Description

The EVAP electrode is an electrosurgical device made of medical grade stainless steel, teflon, new silver, and Hytrel tubing. Some EVAP versions have gold plated rollers.

2.0 Intended Use

These specific EVAP electrodes can be used for vaporization, ablation, coagulation, and or resection of soft tissue in the urology tract and/or fibroids or myomas. The electrodes can be used for endometrial ablation and endometriosis.

3.0 Technological Characteristics

There are no significant technological characteristics of the new device compared to the existing device.

4.0 Substantial Equivalence

The EVAP electrodes are substantially equivalent to devices sold or previously sold by Richard Wolf Medical Instruments, Circon, and ProSurg. Specifically Richard Wolf models approved by 510(k) K953983, Circon model VE-B, and proSurg model SB-24W.

5.0 Performance Data

Devices were tested to meet the appropriate sections of the ANSI/AAMI standard on High Frequency Devices.

6.0 Clinical Tests

Using canine models, it has been shown that coagulation depth increases with higher wattage, but does not exceed 2-3mm. Irrigation reduces the risk of heat damage. Long term morbidity and healing were not known.

7.0 Data Conclusions

The Richard Wolf EVAP Electrode is equivalent to existing electrodes, particularly those approved by the Richard Wolf 510(k) K953983, ProSurg, and ACMI/Circon.

By: Robert L. Casarsa Date: Apr 3, 98

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 10 1998

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

Re: K970961
EVAP Electrodes
Dated: January 16, 1998
Received: January 20, 1998
Regulatory Class: II
21 CFR 884.4160/Procode: 85 KNF

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970961

Device Name: Vaporization Electrodes

Indications for Use:

These specific EVAP electrodes can be used for vaporization, ablation, coagulation, and or resection of soft tissue in the urology tract and/or fibroids or myomas. The electrodes can be used for endometrial ablation and endometriosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970961

Prescription Use ✓
Per CFR 21 CFR 801.103

OR

Over-The Counter Use