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NOV 26 1997

K973295

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:		**Date of Preparation:** August 27, 1997	
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: Bipolar Button Electrode w/ Suction Applicator		**Model number:** 8801.551, 8801.451	
Common name: Bipolar Electrode		**Classification name:** General and Plastic Surgery	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K945805	1 Monopolar/Frazier Suction Probe	1 Wells Endoscopic
2	2	2
3	3	3
4	4	4

1.0 Description

The Richard Wolf Bipolar Button Electrode with Suction Applicator consists of the suction applicator with a suction channel, a button electrode, and the bipolar connector.

2.0 Intended Use

Richard Wolf Bipolar Button Electrode with Suction Applicator is designed for use in plastic and reconstructive surgery. The device provides a method of coagulating small blood vessels that bleed as a result of blunt dissection of tissue subcutaneously. When used in conjunction with the suction applicator, smoke caused by the cauterization of tissue is evacuated from the operative site.

Revised 11/12/97

evacuated from the operative site.

3.0 Technological Characteristics

- Electrical current is confined to between the two prongs at the distal tip of the instrument which prevents the electrical current to migrate to critical anatomy in the facial area.
- Working length of 150 mm and 280 mm
- Suction applicator diameter is 3 mm

4.0 Substantial Equivalence

The Richard Wolf Bipolar Cautery and Suction Tube has the same intended use as the Wells Endoscopic Company's Monopolar/Frazier Suction Probe.

5.0 Performance Data

Abrasion/Flaking testing was performed to assure the integrity and bonding of the insulation material to the instruments.

6.0 Clinical Tests

None

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 L. Casarsa Date: Aug 27, 97

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1997

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

Re: K973295
Trade Name: Bipolar Button Electrode w/Suction Applicator
Regulatory Class: II
Product Code: GEI
Dated: August 27, 1997
Received: September 2, 1997

Dear Mr. Casarsa:

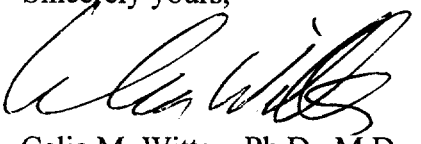
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4595. 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,



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): K973295

Device Name: Bipolar Button Electrode with Suction Applicator

Indications for Use:

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973295

Prescription Use ✓
(Per 21 CFR 801.109)

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