

K983236

DEC 4 1998

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION

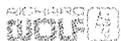


510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: September 15, 1998	
Company / Institution name: Richard Wolf Medical Instruments Corp.		FDA establishment regulation 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 HF Cable		Model number: 8108.xxx	
Common name: Bipolar HF Cable		Classification Name: Bipolar HF Cable	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K943776	1 Bipolar Cables 8108	1 Richard Wolf GmbH	
2 pre-enactment	2 Bipolar Cables 8108	2 Richard Wolf GmbH	
3	3	3	
4	4	4	

1.0 Description

The Bipolar HF Cables are used to direct a high frequency electrical current from an electrical generator made by unspecified manufacturers to a R. Wolf HF instrument.





2.0 Intended Use

The Bipolar HF Cables are used to connect adequately equipped R.Wolf HF instruments to the corresponding HF devices.

3.0 Technological Characteristics

The bipolar HF Cables may be operated at a maximum recurrent peak voltage of 4000 Vp and the bipolar cables at a maximum 1000 Vp.

The cables can be sterilized by steam at 134°C.

4.0 Substantial Equivalence

Bipolar HF Cables 8108 are substantially equivalent to Bipolar HF Cables cleared on K943776. The material changes have not reduced safety or effectiveness.

5.0 Performance Data

No known FDA performance standard exists.

The Bipolar HF Cables were tested to comply with the appropriate sections of ANSI/AAMI standard on high frequency devices, HF18 and IEC601-2-18.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manuals.

By: _____

Robert L. Casarsa
Quality Assurance Manager

Date: _____



DEC 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983236
Trade Name: Bipolar HF Cable
Regulatory Class: II
Product Code: GEI
Dated: September 15, 1998
Received: September 15, 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.

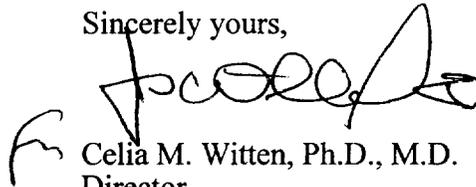
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Robert L. Casarsa

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' on the left side.

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):

K983236

Device Name:

Bipolar HF Cable

Intended Use:

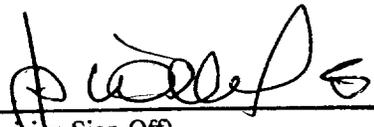
The Bipolar HF Cables are used to connect adequately equipped R.Wolf HF instruments to the corresponding HF devices.

Contraindications:

Contraindications directly related to the product are currently unknown. For further information refer to the latest medical literature.

(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 K983236

Prescription Use
Per 21 CFR 801.109

OR
2 - 1

Over-The Counter _____