

K972519

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: July 7, 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: Unipolar HF Grasping Forceps		Model number: 8254.601/.602	
Common name: Forceps		Classification name: Forceps, ENT	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 Pre-amend.	1 Grasping forceps, 8283.12/.13	1 Richard Wolf	
2	2 Grasping Forceps, 8660A	2 Karl Storz	
3	3 Miniature Grasping Forceps, 8593	3 Karl Storz	
4	4 Grasping Forceps, 50-6858	4 Pilling-Weck	

1.0 Description

The forceps are made of medical grade stainless steel, teflon coated medical grade stainless steel, black chrome plating, and plastic.

2.0 Intended Use

The instruments are for use on the laryngeal anatomy, e.g., the vocal cords, false cords, surraglottis, glottis, epgilottis, tongue base, oral pharynx, and uvula. The instruments are used to grasp and hold tissue for dissection or vaporization. The forceps may be used to coagulate blood vessels within the tissue when it is connected to a unipolar high frequency generator. Depending on where the bleeding vessel is located, coagulate by applying a low dose of HF current. The intensity depends on the severity of the bleeding and on the vessel. Always start with a low dosage and increase the power if necessary.

3.0 Technological Characteristics

The grasping forceps have been insulated and now allow the application of high frequency current.

4.0 Substantial Equivalence

The submitted devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf, Karl Storz, and Pilling Weck.

5.0 Performance Data

None

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The forceps are substantially equivalent to other non-cautery capable forceps available on the market.

By: _____

Robert L. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: _____

July 2, 97



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 1997

Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, Illinois 60064

Re: K972519
Unipolar HF Micro Grasping Forceps
Dated: July 7, 1997
Received: July 7, 1997
Regulatory class: II
21 CFR 878.4400/Procode: 79 GEI

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.

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/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

INDICATIONS FOR USE

510(k) Number (if known): K972519

Device Name: Unipolar HF Grasping Forceps for Laryngeal Microsurgery

Intended Use:

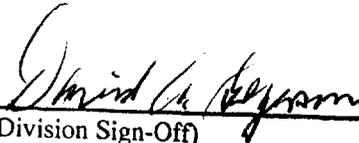
The instruments are for use on the laryngeal anatomy, e.g., the vocal cords, false cords, surraglottis, glottis, epiglottis, tongue base, oral pharynx, and uvula. The instruments are used to grasp and hold tissue for dissection or vaporization. The forceps may be used to coagulate blood vessels within the tissue when it is connected to a unipolar high frequency generator. Depending on where the bleeding vessel is located, coagulate by applying a low dose of HF current. The intensity depends on the severity of the bleeding and on the vessel. Always start with a low dosage and increase the power if necessary.

Contraindications:

Do not use in the presence of flammable anesthetics.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972519

Prescription Use _____
Per 21 CFR 801.109

OR

Over-The Counter _____