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K980129

NOV 5 1998

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** January 12, 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: EPS. Instruments for Endoscopic Plastic Surgery		Model number: See section 1. Submitted Devices	
Common name: Endoscopic and Reconstructive Plastic Surgery		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 pre-enactment	1 several devices	1 Richard Wolf
2	2 EndoPlastic Instruments	2 SnowdenPencer
3	3 Endoscopic Plastic Surgery Instruments	3 Wells
4	4 Plastic & Reconstructive Surgery Instruments	4 Padgett

1.0 Description

The EPS instruments consist of endoscopes, irrigation/suction cannulas/ sheaths and holders for the endoscope, retractors, forceps, and electrodes (in addition to the exempt dissectors, elevators, probes, and forceps).

2.0 Intended Use

Endoscopes are designed to visualize anatomy through natural and man-made openings in body cavities.

Retraction Sheaths are used to form an artificial working access. The introduction of a telescope permits illumination and observation of the operating site. The rotatable stopcock permits continuous irrigation. The retraction sheaths are used in endoscopic plastic surgery in endo-facelift, eyebrow and forehead lift specialties.

The Obturator (mandrin) is used in conjunction with the sheath for atraumatic insertion into body cavities.

The Optical Retractors are used to maintain a subcutaneous space during surgical procedures, for plastic/cosmetic and reconstructive surgery. They can be combined with an endoscope to visualize the tissue and anatomic structures.

The Optical Holders with optical retractors allow single-handled maintenance of subcutaneous pocket while providing traction. One hand is free for dissection. The optical holder or a guide holds the endoscope in position under the blade of the retractor.

Suction/Irrigation Instruments are used to keep the operating site and the endoscope free of blood and secretion; at the same time it serves as a retractor to hold tissue out of the way. The instrument is used in endoscopic surgery of the nose, nasal sinuses, and in endoscopic plastic surgery.

The Micro Grasping Forceps with HF are used to grasp and to coagulate small blood vessels.

The HF Coagulation Suction Aspirator suctions and coagulates while holding tissue out of the way during the endoscopic operation, e.g. of the larynx in connection with CO_2 lasers, in mediastinoscopy or in plastic surgery.

The Bipolar Coagulation suction Tube (bipolar aspiration tube) is used for aspiration and coagulation of small lesions.

The Bipolar Coagulation Instrument is designed for used in plastic/cosmetic and reconstructive surgery to coagulate small blood vessels that bleed from blunt dissection of subcutaneous tissue. Smoke caused by cauterization of tissue is evacuated from the operative site when used in conjunction with the suction applicator.

Bipolar electrodes are used to coagulate and to remove or destroy tissue by the use of bipolar HF current.

3.0 Technological Characteristics

The cannula of the **retraction sheath**, in combination with the endoscope, allows visualization and retraction. The single port with rotatable cock allows both irrigation and suction irrigation and placed on the surgeon's non-dominant side. ***What does the last part of the sentence mean?***

4.0 Substantial Equivalence

The devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf and 510(k) devices sold by Karl Storz.

5.0 Performance Data

No data generated. The bipolar instruments are developed to conform to the standards 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 Date: 1/8/98

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 1998

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

Re: K980129
Trade Name: Instruments for Endoscopic Plastic Surgery
Regulatory Class: II
Product Code: GCJ
Dated: August 06, 1998
Received: August 07, 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.

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

Indications for Use

510(k) Number (if known): K980129

Device Name: Instruments for Endoscopic Plastic Surgery (EPS)

Intended Use:

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices K980129
510(k) Number

Prescription Use
Per 21 CFR 801.109

OR

Over-The Counter___

Suction/Irrigation Instruments are used to keep the operating site and the endoscope free of blood and secretion; at the same time it serves as a retractor to hold tissue out of the way. The instrument is used in endoscopic surgery of the nose, nasal sinuses, and in endoscopic plastic surgery.

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Bipolar electrodes are used to coagulate and to remove or destroy tissue by the use of bipolar HF current.

Contraindications:

There are no known contraindications directly related to the product. The attending physician must consider the general condition of the patient when determining if the application is appropriate. Refer to the current technical literature for additional instructions.

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980129

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