AUG 27 1998

1973943

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: October 10, 1997
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: Instruments for Endoscopic Subfascial Harvesting of Veins (ESHV) and Endoscopic Subfascial Discision of Perforating Veins (ESDP)	Model number: 8781, 8393, 8394 and others
Common name: Operating Tubes, Operating Telescope Laser Guide, Knife	Classification Name: Endoscopes and Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K964258	1 Instruments for Endoscopic Subfascial Discision of Perforating Veins "ESDP", Model 8781	1 Richard Wolf
2	2 See section 3, Equivalent Devices	2
3	3	3
4	4	4

1.0 Description

The Instruments for endoscopic subfascial Harvesting of Veins (ESHV) and Endoscopic Subfascial Discision of Perforating Beins (ESDP) consists of operating telescopes, endoscopic operating tubes, laser guide, hook knife, various monopolar and bipolar grasping forceps and scissors, and veins dissector (stripper).

2.0 Intended Use

The ESHV (Endoscopic Subfascial Harvesting of Veins) instrument set is used for minimally invasive preparation and harvesting of the veins for use in cardiac and vascular surgical procedures. The intervention takes place under sterile conditions.

The Veins dissector (stripper) is used for the blunt preparation of tubular structures, specifically for the free-preparation of vessels, e.g. the vein saphena magma.

The ESDP (Endoscopic Subfascial Discision of Perforating Veins) instrument set is used for minimally invasive visualization, diagnostic, and therapeutic procedures of subfascial veins in the lower extremities, e.g. the saphenous vein. The intervention takes place under sterile conditions.

3.0 Technological Characteristics

There are no new technological changes on the submitted devices compared to the existing devices. The EDHV endoscope, tubes, and instruments are longer than the ESDP.

4.0 Substantial Equivalence

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

5.0 Performance Data

Performance data not generated.

6.0 Clinical Tests

No clinical tests performed.

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: Oct 10, 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

AUG 27 1998

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

Re: K973943
Instruments for Endoscopic Subfacial Harvesting of Veins and Endoscopic Subfacial Discision of Perforating Veins
Regulatory Class: II (two)
Product Code: 78 GCJ
Dated: June 23, 1998
Received: June 24, 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 legally marketed predicate 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) 594-4648. 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" (21CFR 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K973943

Device Name: Instruments for Endoscopic Subfascial Harvesting of Veins And Endoscopic Subfascial Discision of Perforating Veins

Intended Use:

The ESHV (Endoscopic Subfascial Harvesting of Veins) instrument set is used for minimally invasive preparation and harvesting of the veins for use in cardiac and vascular surgical procedures. The intervention takes place under sterile conditions.

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The ESDP (Endoscopic Subfascial Discision of Perforating Veins) instrument set is used for minimally invasive visualization, diagnostic, and therapeutic procedures of subfascial veins in the lower extremities, e.g. the saphenous vein. The intervention takes place under sterile conditions.

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.

Combinations:

Auxiliary instruments from 3.5 mm to 5.5 mm diameter are used through the operation channel. Refer to the corresponding auxiliary instruction manuals.

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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K973943

Prescription Use
Per 21 CFR 801.109

OR

Over-The Counter____