OCT 1 9 2001

K012309

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RICHARD WOLF
Medical Instruments Corporation

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
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510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: July 18, 2001
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: RIWO System Trays	Model number: See section 3, "Submitted Devices"
Common name: Trays for Sterilization, Storage and Transport	Classification Name: Accessories, cleaning, for endoscope

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enact.	1 Instrument Container 8582.06, 8584.06	1 Richard Wolf
2	2 Micropac, Endopak, Scopepak, Multipak	2 Riley
3	3 Scope trays, Silicone Nipple Mat System, Standard Sterilization Containers	3 Transmedica
4	4 C.A.S.E. System: Containers and Baskets	4 Genesis
5	5 Instrument Protection and Sterilizing System	5 Micromedics

1.0 Description

The devices are assorted open or closed trays for sterilization, storage and transport.

2.0 Intended Use

The **RIWO SYSTEM TRAYs 3820x.xxx** have been designed

- to be equipped as required
- for steam and EtO sterilization
- for sterile storage
- for transport

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3.0 Technological Characteristics

The **RIWO System Trays** are blue in color. The assorted trays vary in size and begin with product number 3820x.xxx. Other characteristics are a base, latched cover and silicone peg mat construction. These trays hold the device to be sterilized and the tray must be wrapped for sterilization and sterile storage. They can be used in steam or ethylene oxide sterilization.

4.0 Substantial Equivalence

These devices are substantially equivalent to existing pre-enactment devices and 510(k) devices sold by Richard Wolf and 510(k) devices sold by Riley, Transmedica, Genesis, and Micromedics.

5.0 Performance Data

The steam sterilization tests performed by Richard Wolf show that the steam sterilization has no influence on the functional performance of the submitted devices when using the pre-vac method.

The EO sterilization tests performed, shows that the ethylene oxide sterilization has no influence on the functional performance of the submitted devices.

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: July 18, 2001

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K012309
Trade/Device Name: RIWO System Trays for Sterilization and Transport
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR §880.6850
Regulation Name: Sterilization wrap
Regulatory Class: II
Product Code: 78 FEB and KCT
Dated: July 18, 2001
Received: July 23, 2001

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K012309

Device Name: Trays for Sterilization

Intended Use:

The RIWO System Trays 38201.xxx, 38202.xxx, 38301.xxx have been designed to hold devices during sterile storage, transport, and while undergoing steam and ethylene oxide sterilization.

Material Composition: PSU granulate UdelP-1700, PPSU granulate Radel R 5000, silicone, medical grade stainless steel, polyester foil

Physical Properties: The instrument container ranges in height from 60mm to 100mm. The tray system consists of:

- perforated instrument container with peg mat inlay
- spring catches
- perforated lid w/ fixed peg mat
- coding plate for container & lid
- marker pen

Specifications: The inner dimension of the trays range from a length of 300mm to 705 mm and widths of 120mm to 200mm.

The outer dimensions of the trays range from a length of 366mm to 766mm; widths of 150mm to 266mm; and heights range from 47mm to 103mm.

Design: The RIWO System Trays are designed as an accessory for housing and holding endoscopes and instruments. The design provides spaces to position the devices without placing them on top of each other; thus, reducing the potential for damage during sterile storage, transport, and sterilization. They are designed as an aid to sterilization. The trays with the included endoscope/instruments must be wrapped in sterile packaging material (in accordance with DIN 58953). The wrapping, not part of this submission, maintains sterility and barrier integrity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012309

Prescription Use ✓ OR Over-The Counter