AUG 3 2012

Revision 08-01-2012

K120898

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510(k) Summary

Submitter:			Date of Preparation: **August 1, 2012**
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. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			
Parent Company:			
Company / Institution name: **Richard Wolf GmbH**			FDA establishment registration number: 96 111 02
Street address: Pforzheimer Str. 32			
City: Knittlingen	State/Province: Baden-Württemberg	Country: Germany	ZIP / Postal Code: 75438
Product Information:			
Trade name: KeyPort AR System			Model number: 8850XX, 89XX
Common name: Anoscope and accessories Laparoscope & General Plastic Surgery Laparoscope & Single Port Access Device			Classification name: 876.1500, FER - Anoscope and accessories GCJ - Laparoscope & General Plastic Surgery OTJ - Laparoscope & Single Port Access Device

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K110792	1 Gelpoint Path (Product Code FER)	1 Applied Medical Resources Corp
2 K103253	2 Sils Port (Product Code GCJ, FER)	2 Covidien (Formerly US Surgical)
3 K000180	3 TEM Combination System and Instrument Set (Product Code FJL, GCM)	3 Richard Wolf Medical Inst. Corp.
4 K090275 (K014047)	4 Gelport Single Incision Access System (Product Code GCJ)	4 Applied Medical Resources Corp
5 K110004	5 ASC Triport & Laparoscopic Access Device (Product Code OTJ, GCJ)	5 Advanced Surgical Concepts.

Device Description:

The KeyPort AR System is a reusable device used for creating and maintaining an artificial access port to body cavities including the necessary pneumoperitoneum. The KeyPort AR System allows multiple instruments and /or camera access during minimally invasive procedures, which include anal-rectal procedures such as Transanal Endoscopic Microsurgery (no incision). This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately trained persons.

The KeyPort AR System is comprised of KeyPort silicone sealing insert (1), KeyPort AR trocar sleeve (2), and KeyPort trocar (3). The KeyPort AR System is used in conjunction with CO_2 insufflator, Pump for smoke gas evacuation, and required instruments which are selected in accordance with the indications as well as the surgeon's requirements.

Unless otherwise specified, all components of the KeyPort AR System are reusable and require sterilization before use. Methods of cleaning, disinfection, and sterilization are detailed in Instruction Manual GA-B 253-2 USA.

Intended Use:
The KeyPort AR System access device is an endoscopic accessory intended for use as a multiple instrument and/or camera port during minimally invasive anal-rectal procedures such as Transanal Endoscopic Microsurgery (no incision).

Technological Characteristics:
The KeyPort AR System is technologically similar to devices found in this submission in that all/some of the devices:

- Have insufflation capability,
- Will maintain pneumoperitoneeum / pneumorectum,
- Have smoke evacuation capability,
- Have 3 ports that can seal against insufflation pressure as instruments are inserted.
- Have ports which are in a fixed position and are flexible in design,
- Have ports that can accommodate laparoscopic instruments which vary in size from 5mm - 15mm,
- Is capable of being sutured to the patient to assist with retention,
- Are made of materials which meet USP Class VI, ISO 10993-1 requirements and are latex free,
- Requires a trocar (introducer) for insertion into body cavity,
- Are reusable and must be sterilized prior to each use.

The KeyPort AR System is technologically different to devices found in this submission in that:

- KeyPort trocar sleeve is rigid in design and is available with or without retention threads.

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Performance Data:
Sterilization validations were conducted for the Richard Wolf KeyPort AR System. All acceptance criteria were met.

Gas-tight seal testing verified acceptable results for a pressure up to 20mmHg, results from preclinical test using pigs show that an incision of 20mm is sufficient.

The submitted device is very similar to predicate devices found in this submission and the indications are well known. Therefore, no additional performance testing is necessary to demonstrate substantial equivalence.

Clinical Data:
No clinical tests performed.

Rational for Substantial Equivalence:
The Richard Wolf KeyPort AR System shares the same general indications for use, have similar function features and technological characteristics as the predicate devices, minor difference(s) do not raise new questions for safety or effectiveness. For these reasons, the Richard Wolf KeyPort AR System is substantially equivalent to the existing 510(k) cleared devices sold by: Applied Medical Resources Corporation (K110792, K090275), Covidien (K103253), Richard Wolf Medical Instruments Corporation (K000180), and Applied Medical Resources Corporation (K110004).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 3 2012

Richard Wolf Medical Instruments Corporation
% Mr. Ron Haselhorst
Quality Assurance, Regulatory Affairs Manager
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K120898
Trade/Device Name: KeyPort AR System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: June 21, 2011
Received: July 05, 2011

Dear Mr. Haselhorst:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120898

Device Name: KeyPort AR System

Intended Use:

The KeyPort AR System access device is an endoscopic accessory intended for use as a multiple instrument and/or camera port during minimally invasive anal-rectal procedures such as Transanal Endoscopic Microsurgery (no incision).

Prescription use ✓ and / or Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDHR office of Device Evaluation (ODE)

Neil R.P. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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