510(k) Summary

Submitter:			Date of Preparation: **April 10, 2009**
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 5803
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			
Product Information:			
Trade name: 3 CCD HD Endocam 5550		Model number: 5550	
Common name: Endoscopic Video Camera System.		Classification name: Endoscope and Accessories, Class II (21 CFR 876.1500, Product Code GCJ)	

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K063457	1 TrueHD Digital Camera System	1 ConMed Linvatec
2 K023659	2 1 CCD Endocam 5520 System	2 Richard Wolf Medical Instruments Corp.

Device Description:

The 3 CCD HD Endocam 5550 consists of a camera control unit and a connectable camera head. The camera head connects to an endoscope for High Definition visualization during minimally invasive surgical procedures.

The camera controller provides outputs for video monitoring, video recording, and connecting to the RWMIC-NET Operating Room Control System.

Intended Use:

The 3 CCD HD Endocam 5550 has been designed for video endoscopy and can be used for both diagnostic and therapeutic interventions. In conjunction with video recorders, video printers and other video devices it can be used for recording and storing video images.

Indications and Field of Use:

The 3 CCD HD Endocam 5550 is intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, gynecologic, laparoscopic, urologic, sinuscopic, plastic, and as an accessory for microscopic surgery.

Technological Characteristics:

The technology of the Richard Wolf 3 CCD HD Camera System is similar if not identical to the technology of the referenced predicate device HD Camera Systems as they utilize the similiar components.

The camera system uses a High Definition Camera head progressively scanned. All pixel information from each CCD is scanned sixty times a second and there are more than 700,000 pixels.

The camera controller provides High Definition Serial Digital Interface (HD-SDI) and Digital Video Interface (DVI) ports for connection to a High Definition monitor in a 720p 1080I & 1080P with either a 5 x 4 or 16 x 9 aspect ratio format. This type of technology is similar to all High Definition camera systems.

Sterilization:

The camera head is to be sterilized prior to each procedure using a sterilization method defined in instruction manual BB-A 253-1 US.

The camera controller is to be cleaned with a soft cloth moistened with surface disinfectant, alcohol or spirit as defined in instruction manual GA-A 253-US.

Substantial Equivalence:

The Richard Wolf Medical Instruments Corporation 3 CCD HD Endocam 5550 is substantially equivalent to the ConMed Linvatec HD Digital Camera System (K063457) and Richard Wolf Medical Instruments Corp.CCD Endocam 5520 System (K023659) due to the fact that they both utilize similar camera system components and technology as the CCD HD Endocam 5550 for the same approved intended uses. Further, CCD HD Endocam 5550 introduces now new patient risks or concerns.

Performance Data:

Bench testing of specifications were verified / validated and software validation was performed to assure safe and effective operation / control of the software functions.

Clinical Data:

No clinical data was required to confirm safety and effectiveness.

Conclusion:

Testing has shown that the Richard Wolf 3 CCD HD Endocam 5550 performs to its specifications, operates as intended, is safe and effective, and is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Richard Wolf Medical Instruments Corporation
% Underwriters Laboratories, Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K080977
Trade/Device Name: 3 CCD HD Endocam 5550
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 6, 2008
Received: May 7, 2008

Dear Mr. Devine:

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 such 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 Section 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indication for Use

510(k) Number (if known): K080977.

Device Name: 3 CCD HD Endocam 5550.

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

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080977