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5. 510(k) Summary

Submitter:			Date of Preparation: 25. February 2008 Revised: 05. June 2008
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: IL 60061
Contact name: Mr. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			

Product Information:

Trade name: POWER DRIVE ART1 2304 with motor handles, tools and Accessories	Model number: 2304.xxx, 8995X.xxx, 8564.xxx, 8996X.xxx,8997X.xxx, 8998X.xxx, 4997X.xxx
Common name: Surgical instrument Motor Unit and accessories/attachments for endoscopy	Classification name: Surgical instrument motors and accessories/attachments.

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K030082	1 Power Control 2303 with Power Stick M4	1 Richard Wolf
2 K871250	2 Intra-articulated arthro power system 2161	2 Richard Wolf
3 K970088	3 RIWO DRIVE Generator with Footswitch, Motor handles and Single Use Rotary Blades and Abraders	3 Richard Wolf
4 K984304	4 RIWO DRIVE Generator, single use or reusable Rotary Cutters and Burrs	4 Richard Wolf
5 K984521	5 RIWO DRIVE small handle	5 Richard Wolf
6. K030009	6. Powershaver SL	6. Karl Storz
7. K062849	7. DYONICS Power II Shaver System	7. Smith & Nephew

1.0 Description

The POWER DRIVE ART1 2304 is an enhanced version of our POWER CONTROL 2303, cleared in K030082. The new device has new electronics, new software, additional motor handles, tools and tool holders such as rotary blades/ abraders, saws, sagittal and reciprocal saw attachments, drill chucks, drills and surgical wires.

2.0 Intended Use

Intended use: In conjunction with a motorized handle (e.g. Power Stick M5/3), the POWER DRIVE ART1 2304 serves as a drive unit for Richard Wolf rotary blades/abraders for the removal of tissue during endoscopic intervention. Simultaneous evacuation (suction) allows continuous removal of the ablated tissue. In conjunction with Power Drill M1, bones can be severed or machined.

Indications and field of use: The product is used in conjunction with endoscopic accessories for the following purposes:

- In arthroscopy, e.g. resection of the meniscus, for removing soft tissue as well as intraarticular severing or abrasion of bone tissue (e.g. ACL or shoulder applications).
- In thoracic surgery, e.g. for the removal of hematomas.
- In sinus surgery, e.g. for the removal of polyps.
- In spinal surgery (arthroscopic microdiskectomy (AMD) for removing degenerated tissue.

3.0 Technological Characteristics

The POWER DRIVE ART1 2304, consisting of: generator, motor handles, tools (such as rotary blades/ abraders, sagittal and reciprocal saws, drills and surgical wires) and tool holders (such as sagittal and reciprocal saw attachments and drill chucks).
Additional features are new motor handles, some with integrated keypad as well as automatic tool recognition with the new rotary blades and abraders (via RFID technology) and a touch screen for user control.
Multiple use devices are not provided sterile; they must be sterilized per their instruction before each use. Single use devices are provided sterile and are marked and designed for only one use on or in a single patient.
Via the integrated CAN-BUS interface, the POWER CONTROL 2304 can be integrated into the R.Wolf RIWO NET SYSTEM with remote control, speech control, and touch-screen monitor.

4.0 Substantial Equivalence

The submitted POWER Drive 2304 generator have same indications, equivalent design, functions and materials as the previous devices sold by Richard Wolf. The new device has new electronics, new software, additional motor handles, tools and tool holders.
Additional features are new motor handles, some with integrated keypad as well as automatic tool recognition for the new rotary blades and abraders. Together with the touch screen control, this increases the user comfort and avoids damage caused by incorrect settings.
The new inner sheaths of the rotary blades and abraders have a DLC (diamond-like carbon) coating to reduce friction. The housing of the new drill is made of anodized Aluminum. .
Submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-cleared devices sold by Richard Wolf, Karl Storz, and Smith & Nephew

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5.0 Performance Data

No performance standards are known.

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 instructions manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

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

Re: K080617
Trade/Device Name: POWER DRIVE ART1 2304 with motor handles, tools and Accessories
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX, HWE, ERL, GEY
Dated: June 5, 2008
Received: June 13, 2008

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.

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

K080617

Indications for Use Statement

510(k) Number (if known): _____

Device Name: POWER DRIVE ART1 2304 with motor handles, tools and Accessories

Intended use: In conjunction with a motorized handle (e.g. Power Stick M5/3), the POWER DRIVE ART1 2304 serves as a drive unit for Richard Wolf rotary blades/abraders for the removal of tissue during endoscopic intervention. Simultaneous evacuation (suction) allows continuous removal of the ablated tissue. In conjunction with Power Drill M1, bones can be severed or machined.

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- In sinus surgery, e.g. for the removal of polyps.
- In spinal surgery (arthroscopic microdiskectomy (AMD) for removing degenerated tissue.

Prescription Use ____✓____ AND/OR Over-The Counter Use_____

(Part 21CFR 801 Subpart D) (Part 21CFR 801 Subpart C)

(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 General, Restorative, and Neurological Devices

510(k) Number K080617