MAR 2 1 2003

K022198

12.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **July 1, 2002**
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. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: Endoscope set for magnetic resonance (MR)		Model number: 8767.412, 8767.121, 8767.452	
Common name: Endoscopes, rigid		Classification name: Endoscopes, neurological	

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K970162	1 Neurological Endoscope Set	1 Richard Wolf
2 K973405	2 Endoscopic Spine System	2 Richard Wolf

1.0 Description

The submitted endoscope set is equivalent to standard endoscopes with a working channel, but for the use in magnetic resonance applications.

2.0 Intended Use

The MR Endoscope by Tronnier (Magnetic Resonance) allows visual observation of the operating site with simultaneous utilization of the working, supply and drain channels.

The Obturator is used for atraumatic insertion of the endoscope.

The MR Endoscope is specially designed for use in open nuclear magnetic resonance tomographs for examination, diagnosis and therapy in neurosurgery in conjunction with endoscopic accessories during intracranial procedures, such as: the fenestration of cysts, the removal of cysts, biopsies of lesions, coagulation of intraventricular lesions, etc.

3.0 Technological Characteristics

The ferromagnetic device materials are replaced by nickel silver or titanium

4.0 Substantial Equivalence

The 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 devices sold by Richard Wolf.

5.0 Performance Data

The devices are conforming to the international standards IEC 601-1 and IEC 601-2-18. Thermal heat rise has been verified to be within acceptable levels.

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.

By: Robert L. Casarsa Date: July 1, 2002

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K022198
Trade/Device Name: Rigid Endoscopes
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: December 20, 2003
Received: December 23, 2003

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.

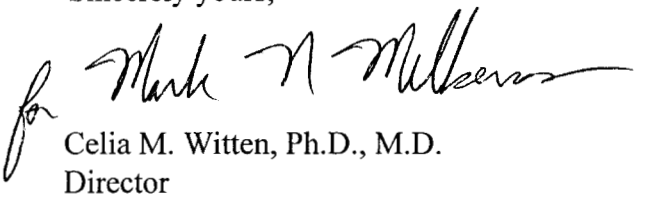
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. 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 Part 807.97) you may obtain. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): — K022198

Device Name: Rigid Endoscopes

Intended use: The MR Endoscope by Tronnier (Magnetic Resonance) allows visual observation of the operating site with simultaneous utilization of the working, supply and drain channels.

The **Obturator** is used for atraumatic insertion of the endoscope.

Indications and field of use: For examination, diagnosis and therapy in neurosurgery in conjunction with endoscopic accessories during intracranial procedures, such as: the fenestration of cysts, the removal of cysts, biopsies of lesions, coagulation of intraventricular lesions, etc.

NOTE: *The MR Endoscope is specially designed for use in open nuclear magnetic resonance tomographs.*

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

Concurrence of CDRH Office of Device Evaluation (ODE)

for Mark N. Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022198

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter _____

(Optional Format 1'2-96)