JUL 2 9 2004

K031858

13 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: 19. September 2003
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: Miniature Neuro-Endoscope System by Hopf and Endoscopic Assisted Neuro Surgery-System		Model number: 8672.xxx, 8768.xxx, and others	
Common name: Neurological Endoscopy Set		Classification name: Neurological endoscope	

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

1.0 Description

The submitted neuroendoscope sets are adaptable and therefore suitable for a variety of surgical manipulations. The set consists of sheaths with working channels respectively working inserts, obturators, endoscopes, forceps, electrodes and an articulated arm.

2.0 Intended Use

The **Miniature Neuro-Endoscope System by Hopf** allows visual observation of the operating site while using working channels, supply and drain channels. They are used for diagnosis and therapy in neurosurgery, in connection with endoscopic accessories, during intracranial procedures.

The **EANS System (Endoscopic Assisted Neuro Surgery)** allows a visualization of cerebral structures not visible through the microscope and at the same time offers the option of supplying and draining irrigation fluid, for examination and diagnosis of microsurgical brain operation.

3.0 Technological Characteristics

The new sets are used with an articulated arm instead of the stereotactic frame, so that they become shorter. The smaller outer diameter and the convenient working length make the endoscope system especially valuable for intraventricular endoscopic procedures in newborn and children, as well as in adults if anatomical situation allows it.

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 510(k)-devices sold by Richard Wolf and competitors.

5.0 Performance Data

The neuroscopy sets are conforming to the international standards IEC 601-1, IEC 601-2-2, and IEC 601-2-18.
To avoid accumulation of heat due to high light energy, only halogen light sources of up to 250 W or other light sources, such as gas discharge lamps, Xenon, of up to max. 180 W must be used, fluid light cables are not allowed to be used.

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: Dec 15, 2003

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061-3110

Re: K031858
Trade/Device Name: Neuro-Endoscope System by Hopf
EANS-System (Endoscopic Assisted Neuro Surgery)
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: II
Product Code: GWG
Dated: May 28, 2004
Received: June 1, 2004

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. 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 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,

for Mark N. Melkerson

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

Indications for Use

510(k) Number (if known): K031858

Device Name: Neuro-Endoscope System by Hopf
EANS-System (Endoscope Assisted Neuro Surgery)

Indications For Use: The **Minature Neuro-Endoscope System by Hopf** allows visual observation of the operating site while using working channels, supply and drain channels. They are used for diagnosis and therapy in neurosurgery, in connection with endoscopic accessories, during intracranial procedures.

The **EANS System (Endoscopic Assisted Neuro Surgery)** allows a visualization of cerebral structures not visible through the microscope and at the same time offers the option of supplying and draining irrigation fluid, for examination and diagnosis of microsurgical brain operation.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

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

510(k) Number K031858