

K970162

OCT 29 1997

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: October 8, 1997		
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. Robert L. Casarsa					
Contact title: Quality Assurance Manager					
Product Information:					
Trade name: Neurological Endoscope			Model number: 8765.001, 15016.299, 15016.300, 15016.301, 8989.401/431, 8765.611, 8765.701		
Common name: Neuro Endoscope 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	1 Gaab Neuroendoscope system Sheath, 83-1521		1 Codman		
2	2 Auero Neuroendoscope system Sheath 28160D		2 Storz		
3	3 Sheath Insert W/ Inflow Stopcock Connection 28160 J		3 Storz		
4	4 Bougie Guide Obturator		4 Storz		
5	5 Telescope Gaab 83-1523		5 Codman		
6	6 Auero system Telescope 27020 A		6 Storz		
7	7 Auero Monoplar coagulating Electrode 27160B		7 Storz		
8	8 Injection Needle 83-1534		8 Codman		
9	9 Suction Catheter 10468 A		9 Storz		
10	10 Neuroendoscope (Ventriculoscope) K941239		10 Asculap		

1.0 Description

The set consists of a sheath, obturators, telescope, forceps, scissors, electrodes, suction needle, and adapters.



2.0 Intended Use

The device is intended for use for direct visualization, diagnosis and therapeutic application during intracranial procedures, such as

- ◆ cyst fenestration
- ◆ shunt placement
- ◆ intraventricular coagulation
- ◆ ventriculostomy of the 3rd ventricle when the aqueduct is obstructed
- ◆ coagulation of small intraventricular lesions
- ◆ biopsy of lesions which lead to the stricture of a ventricle

The instrument simultaneously permits visual control and utilization of a working, an irrigation, and an aspiration channel.

The Neuro-Endoscope can be used with or without a stereotactic frame. A special adapter is available to affix the endoscope.

3.0 Technological Characteristics

- Procedure can be performed through one single burr hole.
- Uses a small flexible endoscope able to pass through the working channel and the possibility of using different rigid telescopes with various viewing angles.
- Rigid telescopes can be advanced in a second stage beyond the tip of the sheath to penetrate small openings or channels and to "look around the corner".

4.0 Substantial Equivalence

The Richard Wolf Neuroendoscopy Set is substantially equivalent to the following devices:

- Codman and Shurtleff, Inc.'s Gaab Neuroendoscope System
- Karl Storz Auero Neuro-Endoscope System
- Aesculap, Inc. Neuroendoscope

All devices have the same intended use.

5.0 Performance Data

- To ensure that the user is electrically isolated from the device, the instruments and connection cables are designed so that the connection instrument/cable overlaps.
- Abrasion/Flaking testing was performed to assure the integrity and bonding of the insulation material to the instruments.
- Testing was performed to verify thermal safety. Thermal damage is unlikely to occur using the Richard Wolf Neuroendoscopy Set.

6.0 Clinical Tests

Clinical tests were performed by Eric Weber, MD, PhD, at the University of South Alabama under protocol # 92-105.



7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instruction manual.

By: _____

Robert L. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: _____

Oct 7, 97



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 29 1997

Re: K970162
Trade Name: Neurological Endoscope
Regulatory Class: II
Product Code: GWG
Dated: October 8, 1997
Received: October 9, 1997

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

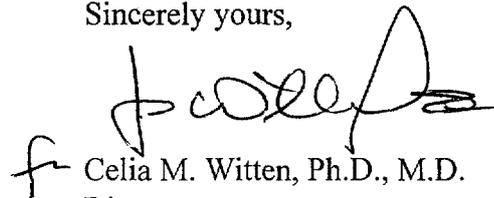
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Robert L. Casarsa

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K970162

Device Name: Neurological Endoscope

Indications For Use:

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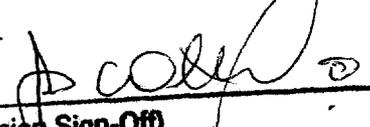
- ◆ cyst fenestration
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K970162

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use