JUL 29 1998



K971340

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:K#971340

1. Submitter's Identification:

Prepared By:
Mr. Yoshihito Shimizu
Product Development Department
Endoscope Division
Olympus Optical Co., Ltd.
2954 Ishikawa-cho
Hachioji-shi, Tokyo, Japan

Date Summary Prepared:

September 8, 1997

2a. Name of the Device:

Olympus Neuro Endoscope

2b Common/Unusual Name:

Neuro Rigid Endoscope

3. Predicate Device Information:

a) Codman Gaso Hopkins Diagnostic Telescope, K#923555
b) Neuro Navigational Neuroview 700R Rigid Scope: K#955037

4. Device Description:

The Olympus Neuro Endoscopes are rigid endoscopes indicated for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

The telescopes and recommended ancillary equipment will be sold non-sterile and can be reused after proper cleaning and sterilization before usage as outlined in the instruction manual.

**Standard Set**

The Olympus Neuro Endoscope standard set includes the following:

Telescope
Instruction Manual

**Optional Accessory**

Trocar for Neuro Endoscopes

The endoscopes are made of stainless steel and are comprised of a combined optical (rod-lens system) and illumination system.

5. Intended Use:

The Olympus Neuro Endoscopes are rigid endoscopes indicated for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

6. Comparison to Predicate Devices:

The intended use of the Olympus Neuro Endoscope is similar to the currently marketed Codman Neuro Endoscope which was cleared for marketing under 510(k) #K923555. Both endoscopes are similar in intended use, design and construction.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing has been performed in accordance with FDA's Reviewer Guidance, 1993, DCRND, specifically IEC-601-1.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

The Olympus Neuro Endoscope is designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC-601-1.

When compared to the predicate devices, the Olympus Neuro Endoscope does not incorprate any significant changes in intended use, method of operation, material, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1998

Olympus Optical Company, Ltd.
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

Re: K971340
Trade Name: Olympus Neuro Endoscope
Regulatory Class: II
Product Code: GWG
Dated: May 28, 1998
Received: June 1, 1998

Dear Ms. Goldstein-Falk:

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.

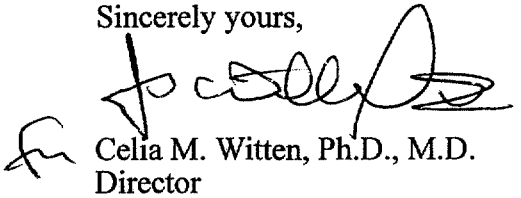
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

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

EXHIBIT A

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510(k) Number (if known): K971340

Device Name: Olympus Neuro Endoscope

Indications For Use:

The Olympus Neuro Endoscopes are rigid endoscopes indicated for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR8O1.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971340