MAR 1 3 2000

MACHIDA MACHIDA ENDOSCOPE CO.,LTD.
13-8, Honkomagome 6-chome, Bunkyo-ku, Tokyo, 113-0021, Japan
Phone:03-3946-2151 Fax:03-3946-2620 E-mail:machida@mbf.sphere.ne.jp

K993568

Premarket Notification [510(K)] Summary

1. Submitter's Name : Machida Endoscope Co., Ltd.

2. Address : 13-8, Honkomagome 6-chome, Bunkyo-Ku, Tokyo, 113-0021 Japan

3. Phone number : 3-3946-2621

4. Fax number : 3-3946-2620

5. Name of contact person : Genichi Kanai

6. Date : October 19, 1999

7. Name of the device:

Trade name/Proprietary name: Machida Flexible Neuro-Endoscope, Model: NEU-4/4L
Common name: Neurological Endoscope
Classification name: Endoscope and Accessories

8. The legally marketed device to which we are claiming equivalence :

Manufacturer: Johnson & Johnson -PROFESSIONAL, INC.
Device Name : CODMAN Steerable Neuroendoscope

9. Description of the device:

Flexible Neuro-Endoscope, NEU-4/4L are mainly desighed for observation and treatment by small instrument which is inserted through the working channel, specifically in the intra-cranium area. The device is mainly constructed with the fiber optic system for imaging and illumination. The device is covered internally by thin stainless spiral plate and outside by a tube so that the flexibility is always maintained.

A-02

The specific features of the device is in its flexibility which facilitates easier insertion process of the device than the rigid one and at the same time provide the operator with the possibility to approach to the observation area quickly so that the operator is able to decide the area which is subject to the treatment.
Different from the rigid device, the flexible device may provide much wider selective choices on what should be done for each clinical cases than the rigid one. The flexible device may be utilized specially in the tortured and complex area which is not accessible simply by other rigid device. This is the main concept why the flexible device was developed.

The device is mainly composed of the control grip, insertion tube, deflecting section, internal working channel, light guide cable and the distal end where the objective lens system are incorporated in addition to the fiber optic imaging and illuminating system. All the material specifically those which are in direct contact with human tissue are proven safe for the medical use.

The above is just an outline of the device and all the details are described in the documentation attached hereto.

10. **Intended use of the device:**

The device is designed for the observation, treatment and recording by photography in the area of cranium such as cerebral ventricle and the neighboring area.

11. **Technological characteristics:**

Common characteristic for Flexible Neuro-Endoscope, NEU - 4/4L

1) High resolution

75° / 80° wide angle of vision is secured with newly designed optical and objective lens system. The clear view is always secured.

2) Improved recording capability

Newly designed ocular lens system provides better conditions for the image recording even when a CCD camera system is mounted onto the scope.

A - 03

3) Maneuverability

Improved maneuverability with shortened apical part and angle deflection with minimum radius. The control grip part is designed for one hand maneuver(operation).

4) Watertightness

Total scope can be immersed in liquid for easy cleaning.

5) Length of light guide cable

The cable has 3000mm length so that it may not be obstructing the maneuver of the scope and accessory.

Specific characteristic for Flexible Neuro-Endoscope, NEU- 4L

1) Various small instruments can be utilized through a large channel for the purpose of treatment in the intra-cranial areas.

12. Performance Standard:

No performance standards or special controls have been developed for this device.

A - 04

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Mr. Genichi Kanai
Executive Managing Director
Machida Endoscope Company, LTD.
13-8, Honkomagome 6-Chome,
Bunkyo-Ku, Tokyo, 113-0021, Japan

Re: K993568/S1
Trade Name: Flexible Neuro-Endoscopes, Model NEU-4/4L
Regulatory Class: II
Product Code: GWG
Dated: February 23, 2000
Received: February 25, 2000

Dear Mr. Kanai:

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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993568

Device Name: MACHIDA FLEXIBLE NEURO-ENDOSCOPES, MODEL NEU-4/NEU-4L

Indications For Use:

MACHIDA Flexible Neuro-Endoscopes, Model NEU-4/NEU-4L are designed to be introduced into the cranium area through the surgically created orifice for the purpose of the observation, the treatment and the recording by photography.

Classification by CER 882 1480 GWG: Class II

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993568