PHILIPS

OCT 13 1998

K980920

Philips Medical Systems

February 24, 1998

510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a 510(K) summary of safety and effectiveness for the following device.

CLASSIFICATION NAME: Stereotaxic Instrument
(Class II; Tier 2; 84HAW, 21CFR 882.4560)

COMMON/USUAL NAME: Image Guided Surgery System

TRADE/PROPRIETARY NAME: *Philips EasyGuide*

ESTABLISHMENT NO.: 1217116

CONTACT PERSON: Peter Altman, Director of Regulatory Affairs

PERFORMANCE STANDARDS:

This device complies with electrical safety standard UL-2601, electromagnetic compatibility standard IEC-601-1-2 and the ACR/NEMA DICOM Version 3 digital imaging communication standard.

SYSTEM DESCRIPTION:

The EasyGuide Neuro (Release 1) Image Guided Surgery Workstation was cleared for marketing via 510(k) 961834. Since then the product structure for EasyGuide has been reconfigured into a basic version known as EasyGuide Standard and options to this version. EasyGuide Standard has also been called EasyGuide Neuro Basic. The EasyGuide Standard Workstation is the same as the EasyGuide Neuro Image Guided Surgery Workstation which was cleared for marketing as noted above. A Neuro (Release 2) option and an EasyTaxis option, which are the subjects of this premarket notification, are options for the Philips EasyGuide Standard Workstation. The Neuro (Release 2) option and the EasyTaxis option extend the functionality and application areas of the EasyGuide Standard Workstation.

INTENDED USE:

The EasyGuide Standard Workstation is intended for planning neurosurgery and for localizing and navigating during neurosurgery. The Easyguide Neuro (Release 2) option and the EasyTaxis option are used for support in neurosurgical procedures such as:

- Frameless stereotactic procedures
- Intra-operative resection of brain tumors
- Biopsies
- Endoscopic procedures

The EasyGuide Neuro (Release 2) option is used for instrument pointing, instrument learning, 3D marker visualization and image rendering when used with the EasyGuide Standard Workstation.

The EasyTaxis option is used to assist the surgeon in the positioning of instruments and in guiding an instrument to its targeted position during a surgical procedure when used with the EasyGuide Standard Workstation.

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SUBSTANTIAL EQUIVALENCE INFORMATION:

The Philips EasyGuide Standard Workstation with the Neuro (Release 2) option and the EasyTaxis option is considered substantially equivalent to the BrainLab VectorVision (K962939), the Zeiss Surgical Microscope Navigator (SMN) (K965139) and the Sofamor Danek StealthStation (K954276). A comparison matrix is provided in Appendix 5 along with commercial brochures for the predicate devices.

SAFETY INFORMATION:

The Philips EasyGuide Standard Workstation with Neuro (Release 2) option and EasyTaxis option is designed to comply with applicable requirements of the Underwriters Laboratories Standard for Safety, X-ray Equipment (UL 2601) and be classified by Underwriters Laboratories. Additionally, the EasyGuide Standard Workstation with Neuro (Release 2) option and EasyTaxis option is in compliance with the ACR/NEMA Digital Imaging Communication (DICOM) standard. The position digitizer laser complies with Title 21 CFR Part 1040.10.

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the August 29, 1991 issue of the "Reviewer's Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review".

Additionally, the Philips EasyGuide Standard Workstation with Neuro (Release 2) option and EasyTaxis option is designed to comply with international standard IEC-601-1-2 for electromagnetic compatibility.

Philips Medical Systems North America Company feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1998

Mr. Frank Gianelli
Senior Regulatory Affairs Specialist
Philips Medical Systems, Inc.
710 Bridgeport Avenue
P.O. Box 860
Shelton, Conneticut 06484-4708

Re: K980820
Trade Name: Philips Neuro (Release 2) Option and EasyTaxis Option for the EasyGuide Standard Workstation
Regulatory Class: II
Product Code: HAW
Dated: July 14, 1998
Received: July 15, 1998

Dear Mr. Gianelli:

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

510(k) Number (if known): 980820

Device Name : **Philips Neuro (Release 2) Option and EasyTaxis Option for the EasyGuide Standard Workstation**

Indications For Use :

The EasyGuide Neuro (Release 2) option is used for instrument pointing, instrument learning, 3D marker visualization and image rendering when used with the EasyGuide Standard Workstation which is indicated for use in planning neurosurgical procedures and for localizing and navigating during neurosurgical procedures.

The EasyTaxis option is used to assist the surgeon in the positioning of instruments and in guiding an instrument to its targeted position during a surgical procedure when used with the EasyGuide Standard Workstation which is indicated for use in planning neurosurgical procedures and for localizing and navigating during neurosurgical procedures.

The Easyguide Neuro (Release 2) option and the EasyTaxis option are used for support in neurosurgical procedures such as:

- Frameless stereotactic procedures
- Intra-operative resection of brain tumors
- Biopsies
- Endoscopic procedures

(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 _____

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

(Optional Format 1-2-96)