JAN 28 1999

PHILIPS

Philips Medical Systems

K981480

April 20, 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 Spine option, which is the subject of this premarket notification, is an option for the EasyGuide Standard Workstation. The Spine option extends the functionality and application areas of the EasyGuide Standard Workstation to include pre-operative planning and intra-operative localizing and navigation during spinal surgical procedures.

The Spine option has the following features:

Hardware:

- Instrument Pointing
- Instrument Learner
- Instrument Switchbox
- Tracker
- Flexible camera pole
- Pedicle Awl

Software:

- 3D marker search
- Registration and tracking functions
- Planning and navigation functions
- Instrument learning

All instruments can be used in the surgical environment. All instruments used in the sterile field can be autoclaved at 134° C. All other parts are easy to clean.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

INTENDED USE:

The EasyGuide Standard Workstation is intended for planning neurosurgery and for localizing and navigating during neurosurgery. **The Easyguide Spine option expands the intended use of the EasyGuide Standard Workstation to include spinal surgical procedures. The EasyGuide Spine option is intended for planning spine surgery and for localizing and navigating during spine surgery.**

SUBSTANTIAL EQUIVALENCE INFORMATION:

The Philips EasyGuide Standard Workstation with the Spine option is considered substantially equivalent to the ISG Viewing Wand (K970865), the Picker ViewPoint (K970604), the Zeiss Surgical Microscope Navigator (SMN) (K965139) and the Sofamor Danek StealthStation (K954276).

SAFETY INFORMATION:

The Philips EasyGuide Standard Workstation with Spine option is designed to comply with applicable requirements of Underwriters Laboratories Standard for Safety of Medical Electrical Equipment (UL-2601) and be classified by Underwriters Laboratories. Additionally, the EasyGuide Standard Workstation with Spine 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 a 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 Spine 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

JAN 28 1999

Mr. Frank Gianelli
Senior Regulatory Affairs Specialist
Philips Medical Systems
710 Bridgeport Avenue
Post Office Box 860
Shelton, Connecticut 06484-0917

Re: K981480
Trade Name: Spine Option for the EasyGuide Standard Workstation
Regulatory Class: II
Product Code: HAW
Dated: November 19, 1998
Received: November 20, 1998

Dear Mr.Gianelli:

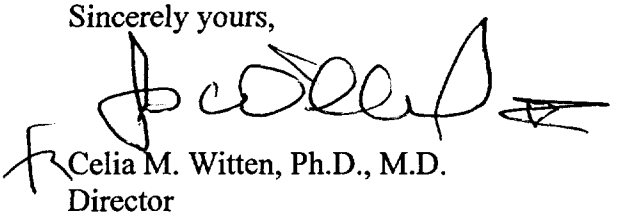
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K981480

Device Name : **Spine Option for the EasyGuide Standard Workstation**

Indications For Use :

The Philips EasyGuide is a viewing and navigation tool for all cranial surgical processes such as

- Tumor resection: Meningioma, Glioma, Pituitary tumor, Skull base tumor, Metastasis
- Treatment of vascular malformations, aneurysms
- Transnasal approaches

The EasyGuide Standard Workstation with Spine option is intended for planning spine surgery and for localizing and navigating during spine surgery.

EasyGuide Spine is specially designed for spinal application areas such as:

- Stabilization techniques
- Tumor resection

(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 K981480

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

(Optional Format 1-2-96)