



# PHILIPS

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**Philips Medical Systems**

## 510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a Summary of Safety and Effectiveness.

Device Name: **Philips EasyGuide Neuro**

Classification Name: **Image Processing System  
Class II (90 LLZ)**

Common/Usual Name: **Image Guided Surgery System**

Establishment Registration No.: **1217116**

Contact Person: **Peter Altman**

Date Prepared: **May 9, 1996**

### System Description:

The **Philips EasyGuide Neuro** is an image guided surgery system for use in planning, localization, and navigation of neurosurgery. The system includes a mobile workstation (based on the Easyvision workstation platform K925950), position digitizer, and dedicated instruments. The workstation is a combination of a Sun SPARC for running the **EasyGuide software** and a computer for processing the data from the position digitizer. The optical position digitizer uses two infrared CCD cameras mounted on a titanium alloy sub-frame and has a laser for easy positioning of the cameras. The instruments (pointers) are equipped with infrared light emitting diodes (LED). Signals from the LEDs are received by the CCD cameras. The computer processes this information and calculates the position, direction, and rotation of the pointer tip in space. The point of space is then shown on the monitor, overlaid on the image generated from the pre-operative scans.

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Registration of the patient's preoperative image with the EasyGuide Neuro geometry during surgery is accomplished through the use of registration markers. These markers are placed on the patient's head before scanning. After the scanning has been completed the images are entered into the EasyGuide Neuro. The markers are left on the patient and prior to surgery, the markers on the patient can be "manually" registered with the markers on the image by placing the pointer on a marker and then selecting the corresponding marker on the image. The Philips EasyGuide Neuro is also capable of performing automatic marker registrations.

**Performance Standards:**

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety, X-ray Equipment (UL 2601) and be classified by Underwriters Laboratories. Additionally, the Philips EasyGuide Neuro will comply with the ACR/NEMA DICOM digital imaging communication standard. The position digitizer laser will comply with Title 21CFR Part 1040.10.

**Substantial Equivalence Information:**

The Philips EasyGuide Neuro is substantially equivalent to the Zeiss MKM (K942233), the Radionics OAS (K951262), and the Elekta/ISG Viewing Wand (K911783). These are all types of image guided surgery devices. The Zeiss MKM is a microscope based navigation system and the Radionics OAS and Elekta/ISG Viewing Wand are mechanical navigation systems. While the EasyGuide Neuro is an optical based navigation system, a commonality exists in that all these systems are indicated for neurosurgical procedures and achieve their intended use through the location of a point in space (in real time) that is correlated with a patient's preoperative images. This ability supports the neurosurgeon in localization, navigation, and planning.

**Safety Information:**

The Philips EasyGuide Neuro system is designed to comply with National and International safety standards as well as the DICOM communication standard. The EasyGuide Neuro system has been extensively investigated during clinical trials in the United States and Europe. It utilizes mature diagnostic imaging technology for the visualization and reconstruction of images, with which the industry and users have many years of experience. The interactive portion (the optical position digitizer) has been tested in both laboratory and clinical environments.

In order to evaluate the benefits and effectiveness of the use of the device, two plannings for neurosurgery were made:

- a planning using conventional means (2D hardcopies on the lightbox) leading to the description of an incision line. This planning was performed prior to using **EasyGuide Neuro**.
- a planning using **EasyGuide Neuro** interactively at the patient. This led to a second incision line.

Both incision lines and planned craniotomy were compared in term of size, shape and location (centering).

The system has shown to be a reliable and safe device in neuronavigation, yielding a mean RMSE = 4.1 mm, for the patient population in the study. Significantly smaller craniotomies were made when compared to conventional (hardcopy based) planning procedures. In cases where there were no significant differences between the conventional and **EasyGuide** planning, still major benefits were experienced ranging from avoiding vascular structures to preservation of functions, such as speech. The overall conclusion is that the results show that **EasyGuide Neuro** is a safe and effective device for use in cranial neurosurgery.

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

#### **Intended Use:**

The **EasyGuide** is intended for planning neurosurgery and for localizing and navigating during neurosurgery. The **EasyGuide** facilitates image-supported decisions that may lead to more effective craniotomies, fewer unforeseen complications and shorter surgery times. As an interactive lightbox, **Philips EasyGuide Neuro** can facilitate image-based decision making. Anatomical structures can be visualized and surgical paths precisely determined before surgery. Decisions on the location and size of a tumor, or an arteriovenous malformation can be made with confidence. Critical areas can be identified and avoided for better access to pathology.

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.