

K960714



510(k) SUMMARY

Contact Information

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Date: 16th February, 1996

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General Information

Classification:

The ISG family of viewing wands are substantially equivalent to other devices within the classification of diagnostic devices (21 CFR 892.1750) that have been reviewed under the provisions of the Medical Device Amendments and are being marketed in interstate commerce. Such devices have been classified as Class II devices.

Classification Name:

Diagnostic Device - Computer Tomography X-ray System (Accessory)

Common/Usual Name:

Image Processing/Surgical Navigation System

Proprietary Name:

ISG Family of Viewing Wands

Predicate Devices:

The Family of Viewing Wands as described in this submission is substantially equivalent to the Allegro Viewing Wand by ISG Technologies Inc. which was the subject matter of 510(k) file #K911783 and which is currently being marketed by ISG Technologies, Incorporated. The Family of Viewing Wands also incorporates some of the features that were previously provided by the CAMRA Allegro workstation (#K901679).

The Family of Viewing Wands incorporates components that are substantially equivalent to other legally marketed devices, including the Zeiss MKM (Multiple Coordinate Manipulator) system (#K942233); the Radionics OAS (Operating Arm System) neurosurgery planning and guidance system (#K951262); and the Codman Acustar I Advanced Surgical Navigation System (#K944612).

Performance Standards:

There are currently no Section 514 performance standards applicable to systems of this type. Standards are defined and tested under the specifications included in this submittal.

Description of the Device:

The ISG Family of Viewing Wands is comprised of a medical imaging workstation that is integrated with a position-sensing user directed probe. This allows for the provision of information pertaining to the current position of the probe related to the surrounding anatomy by correlating pre-operative CT and/or MR imaging data with the intra-operative situation. Once a patient's CT or MR images have been transferred to the workstation, the patient is correlated to that image dataset. The system then displays the orientation of the probe and the position of the tip on the corresponding image, updating the display in real-time as the probe is moved. The Family of Viewing Wands is designed to:

- Process and display pre-operative radiographic images on a monitor.
- Provide intra-operative image control based upon the position and orientation of a user directed probe
- Allow for the optional integration and usage of different position sensing technologies (articulated arm, infrared freehand) and surgical probes (hand-held pointers, surgical microscope).
- Store/retrieve image data on computer access media i.e. hard disks, archive media.
- Transmit data over local and wide area networks.

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The components of the Family of Viewing Wands along with their intended functionality are listed as follows:

1. Workstation - The workstation is designed to store, process and display radiographic image data such that a physician can view and interact with this data electronically in order to derive corroborative information related to the specific anatomy of the patient.
2. Localizing device - The localizing device is designed to provide spatial localization information related to both the orientation of a probe and the position of the probe tip. This information is used by the workstation to control the display of the diagnostic image data, such that a physician can intra-operatively view that data in relation to the patient.
3. Communications Device - The communications device is designed to transmit image data from one workstation to another using the industry standard TCP/IP protocol over industry standard networks and transmission lines: Ethernet, Token ring, T1, ISDN, FDDI, ATM, POTS, etc. For transmission over local area networks (LAN) the communication device is industry standard interface hardware built into the workstation itself e.g. an ethernet card.
4. Archive Storage/Retrieval Device - The archive storage/retrieval device is designed to assume responsibility for ensuring access to a reusable copy of image data. The Family of Viewing Wands does not perform any direct image scanning operations. Image data can be imported from a wide variety of scanners, either through a direct interface or through data transfer using an industry standard storage medium. Examples include floppy disks, hard disks, magnetic tape, optical disks, WORM media (Write Once Read Many), etc. The Family of Viewing Wands supports most industry standard storage devices. Device selection is not inherently restricted by the Family of Viewing Wands, but is associated with the workstation configuration.

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