SUMMARY OF SAFETY AND EFFECTIVENESS
JUL - 3 1996

1. General Information

Classification:	Class II
	Image Processing System
Common/Usual Name:	Image Viewing and Processing Workstation
Proprietary Name:	MR Workstations (ViStar, Montage and OnCall)
Establishment Registration:	Picker International, Inc.
	World Headquarters
	595 Miner Road
	Cleveland, Ohio 44143
	FDA Owner Number: #1580240
	FDA Registration Number: #1525965
Performance Standards:	Not Applicable

2. Intended Uses:

The MR Workstations (including the ViStar, Montage and OnCall) are designed to provide fast and convenient review of DICOM compatible digital images from all six diagnostic imaging modalities (MR, CT, Nuclear Medicine, X-Ray, CR and Ultrasound) and secondary capture as well as post-processing of MR and CT images including multi planar reformatting, angiographic rendering, surface rendering, segmentation/disarticulation and cine display.

When used in conjunction with any of these diagnostic imaging modalities, the indications for use remain unchanged from those defined for that modality.

3. Device Description:

The Picker MR Workstations (ViStar, Montage and OnCall) integrate image review and processing software with a variety of hardware configurations. The software consists of a graphical user interface and post-processing capabilities for MR and CT images including: multi planar reformatting, angiographic rendering, surface rendering, segmentation / disarticulation and cine display. The hardware configurations can be divided into three major types, ViStar, Montage and Oncall. In general, the ViStar line of products are single-monitor workstations which can be equipped with all of the image manipulation and reformatting capabilities described above. The Montage line of products are multi-monitor, multi-modality viewing stations which have limited image manipulation and reformatting capabilities. Finally, the OnCall systems are PC-based for remote viewing and provide image review and cine display.

4. Safety and Effectiveness

The Picker MR Workstations (ViStar, Montage and OnCall) are substantially equivalent to the ViStar (K905070) and the software described with the EDGE/VISTA systems (K931544) in safety and effectiveness. The following chart has been compiled to demonstrate the MR Workstations' substantial equivalence to these devices.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	MR Workstations (ViStar/Montage/OnCall)	Predicate Device (ViStar K905070, EDGE/VISTA K931544)
Computer	ViStar/Montage: DEC/Alpha supecomputer with RISC architecture. OnCall: Pentium class personal computer platform (e.g. IBM Thinkpad 760C)	Stardent 3000 supercomputer using parallel RISC architecture. (K905070)
RAM Memory	ViStar/Montage: Ranges from 32 to 256 MBytes. Expandable for all models. OnCall: 24 MBytes. Expandable to 64 MBytes.	64 MBytes. Expandable to 128 MBytes. (K905070)
Image Storage Capabilities	ViStar/Montage: Disk storage ranges from 0.5 to 2.1 GBytes, Additional Storage, optical disk drive, VCR Interface and 1/2" streaming tape drive available. OnCall: Minimum 760 MBytes of Disk Storage.	760 MBytes disk storage, 1/4" cartridge tape drive, magnetic tape drive. Optional optical disk drive. (K905070)

Parameter	MR Workstations (ViStar/Montage/OnCall)	Predicate Device (ViStar K905070, EDGE/VISTA K931544)
Networking	Ethernet TCP/IP. Supports the DICOM v3.0 imaging/networking protocols.	Ethernet TCP/IP. (K905070)
Filming	ViStar/Montage: Direct and Remote Filming Capabilities. OnCall: Limited formats available.	Direct and Remote Filming Capabilities. (K905070)
Monitor	ViStar/Montage: 17-21" color or greyscale high resolution (1280 x 1024) monitor. 72 Hz, non-interlaced. OnCall: Laptop- Color display with 800 x 600 resolution and SVGA graphics. Desktop- same as ViStar/Montage.	19 inch, 1280 x 1024 high resolution color monitor, 60 Hz, non-interlaced. (K905070)
Graphical Interface	Image review, Database Directory, Draw, Filter, and Filming.	Image review, Database Directory, Draw, Filter, and Filming. (K931544)
Image Utilities	Archive, Delete, CD Player, CT Import, HPQ Import, HPQ Tape Import, Export, Camera Summary, Film Summary, Log Problem, Image Processing, Video Review, Video Capture, System Analysis,	Archive, Delete, Camera Summary, HPQ Import (K931544)

Parameter	MR Workstations (ViStar/Montage/OnCall)	Predicate Device (ViStar K905070, EDGE/VISTA K931544)
Image Manipulation & Reformatting Capabilities	ViStar: Cine Display, Multi planar Reformatting, Angiographic Rendering, Surface Rendering & Cubeview, Segmentation / Disarticulation (Optional). Montage: Cine Display, Multi planar Reformatting, Angiographic Rendering (Optional). OnCall: Cine Display.	Cine Display, Multi planar Reformatting, Angiographic Rendering, Surface Rendering & Cubeview. (K905070)
Intended Use	The **ViStar** systems used with HPQ and 2055HP systems do not change the existing indications which are: The Picker International Vista HPQ and 2055 HP systems are indicated for use as NMR devices that produce images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis. (K905070) The **Picker MR Workstations (including the ViStar, Montage and OnCall)** are designed to provide fast and convenient review of DICOM compatible digital images from all six diagnostic imaging modalities (MR, CT, Nuclear Medicine, X-Ray, CR and Ultrasound) and secondary capture as well as post-processing of MR and CT images including multi planar reformatting, angiographic rendering, surface rendering, segmentation/disarticulation and cine display. When used in conjunction with any of these diagnostic imaging modalities, the indications for use remain unchanged from those defined for that modality.