FEB 10 1997

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

K964626

1. General Information

Classification:	Class II Magnetic Resonance (MR) Imaging System
Common/Usual Name:	Magnetic Resonance Imaging Option
Proprietary Name:	EDGE/VISTA System Enhancement Package
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Cleveland, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The EDGE/VISTA System Enhancement Package does not change the existing indications for the EDGE/VISTA systems as defined below.

The Picker International EDGE and VISTA systems are indicated for use as a NMR device that produces 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.

3. Device Description

The EDGE/VISTA system enhancement package includes changes in the computer subsystem, the gradient subsystem, the RF subsystem, the magnet subsystem, the patient handling subsystem, and the magnet enclosure. The main features provided with this enhancement are a 61 cm body coil, three gradient performance levels, water cooled gradients, an increase in the SAR first controlled operating mode limit, and optional increased reconstruction rates.

4. Safety and Effectiveness

The EDGE/VISTA systems with the system enhancement package are similar in technological characteristics and intended use to EDGE/VISTA systems with standard or high performance gradients. The following chart has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE CHART

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Computer Subsystem	Similar display/database computer, monitor and Ethernet communications systems. Ethernet communications link complies with DICOM v3.0 to allow image transfer to other MR, CT, Nuclear, workstation systems and cameras. Optional packages available for increased image reconstruction rates.	Display/Database computer and scan reconstruction hardware connected together by a dedicated Ethernet communications system. Allows for simultaneous scanning and image reconstruction/ manipulation. Single monitor for system operation and image reviewing. Second Ethernet interface for communication with systems on the external network. (See K931544)
Image Storage Short Term: Archival:	 Same Same	 Magnetic Disk Optical Disk (See K931544)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Gradient Subsystem Gradient Coils:	Water-cooled self-shielded gradient system for all performance levels.	*Standard EDGE*- Air-cooled self-shielded gradient system. (see K931544) *EDGE with High Performance Gradients* - Water-cooled self shielded gradient system (see K954646)
Max. Gradient Strength	16, 20 or 27 mT/m	16 or 27 mT/m
Max. Slew Rate	25, 40, 72 mT/m/msec	25 or 72 mT/m
Gradient Amps:	150 A RMS, 300 A peak, 400 V or 270 A RMS, 440 A peak, 600 V	135 A RMS, 220 A peak, 350 V or 270 A RMS, 440 A peak, 600 V
RF Subsystem DTR Spectrometer:	Same	Single Channel with fast sampling ADC and additional digital filtering. Three additional receive channels are available as an option.
RF Amplifiers:	Single frequency RF amplifiers with increased output power to give equivalent B_1 field with larger body coil.	Single frequency RF amplifiers. (See K931544)
Body Coil	61 cm quadrature multi-conductor transmit/receive coil.	58 cm quadrature multi-conductor transmit/receive coil. (See K931544)
Head Coil	Same	Quadrature multi-conductor receive only. (See K931544)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Receive Only Coil Connection Transmit/Receive Box	Same Same	All receive only coils plug into single couch RF connector. Four receive channels in system. (See K931544)
Magnet Subsystem	Same	Active Shield Magnets offered at 1.5 T and 1.0 T. (See K931544)
Patient Handling	Computer controlled patient transport system with increased weight capacity. New method of patient illumination used to increase patient comfort.	Computer controlled patient transport system. (See K931544)
Magnet Facade	Cylindrical fiberglass enclosure. Hinge on front facade removed.	Cylindrical fiberglass enclosure. Hinged front facade. (See K931544)
Power Distribution Subsystem	Same	Isolation transformer, transient suppression circuitry, and power distribution center all contained in a single cabinet. (See K931544)
Operating Software	Same	UNIX - X Windows based operating software. Graphical User Interface - windows and multi-tasking capability provided. SCAN, VIEW, FILM and UTILITIES operations all accessed from single console. Able to switch between on-going tasks. (See K931544)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Operational Features	Same	SCAN capabilities include: Pilot positioning on three different reference images. Preloaded anatomical protocol categories. VIEW capabilities include: Multi planar reconstruction and curvilinear reformatting. FILM capabilities include: ability to set film formats and load print queue directly from Display/Database computer. (See K931544)
Standard Imaging Sequences	Same	2DFT: Field Echo, Spin Echo, Multiple Echo, Inversion Recovery and FAST. 3DFT: FAST
Acquisition and Reconstruction Techniques	Same	Main features include: Multi-angle oblique, presaturation, phase conjugate symmetry, TrueRes and TrueSlice. (See K931544)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Optional Receive Only Coils	All coils for the EDGE/VISTA are compatible with the system enhancement package. New coils/accessories described in this submission: Quadrature Lower Extremity Coil Coil Combiner	Large Joint Coil Small Joint Coil Volume Neck Coil Quad Spine Coil and Positioner General Purpose Flex Coil Bilateral TMJ Coil (Linear and Phased Array versions) Bilateral Breast Coil C/T/L Phased Array Pelvic Phased Array Head-Neck Vascular Phased Array Flexible Body Coil (Quadrature and Phased Array versions) Quadrature Wrist Coil Shoulder Phased Array (See K931544, K932693, K941996, K944469, K952530, K962117, K963356)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Software Options	Software options are the same except for the following additions: Variable Fast Spin Echo: 2 and 32 echo sequences have been added.	Angiography Cardiac Imaging Variable Fast Spin Echo (4, 8, 16, 48 and 64 echo sequences with minimum TE's of 16 to 32 msec) Gradient-Recalled and Spin-Echo (GRaSE) Technique Echo Planar Imaging (See K931544, K945397, K945828, K954646)
Time Varying Magnetic Field	All gradient performance levels: Normal Operating Mode: dB/dt ≤ 40 T/s First Controlled Operating Mode: 40 T/s < dB/dt ≤ 60 T/s	*Standard EDGE:* dB/dt ≤ 20 T/s for all sequences. (see K931544) *EDGE with high performance gradients*: Normal Operating Mode: dB/dt ≤ 40 T/s First Controlled Operating Mode: 40 T/s < dB/dt ≤ 60 T/s (see K954646)

ITEM	EDGE/VISTA with System Enhancement Package	Predicate Devices EDGE/VISTA (K931544) & High Performance Gradients Option (K954646)
Radiofrequency Absorption	Normal Operating Mode: Limited to a maximum level of 1.2 W/kg. First Level Controlled Operating Mode: Limited to a maximum value of 3.2 W/kg. Change in method for acquiring the RF scale factor.	Normal Operating Mode: Limited to a maximum level of 1.2 W/kg. First Level Controlled Operating Mode: Limited to a maximum value of 2.4 W/kg. (See K931544)
Acoustic Noise Typical Worst Case	 80.6 dBA (average) 93.3 dB (peak) 115.1 dBA (average) 123.8 dB (peak)	 90.7 dBA (average) 100.0 dB (peak) 118.7 dBA (average) 125.6 dB (peak) (See K931544)