K971884

AUG 2 0

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II - Magnetic Resonance Imaging System
Common/Usual Name:	Magnetic Resonance Imaging System
Proprietary Name:	ASSET APOLLO
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, 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 ASSET APOLLO does not change the existing intended use for the ASSET system as defined below.

The Picker International ASSET system is intended 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 ASSET APOLLO MR system includes the following enhancements: a water cooled gradient system, increased gradient performance, increased scan/reconstruction rates, and a user selectable bandwidth option.

4. Safety and Effectiveness

The ASSET APOLLO is similar in technological characteristics and intended use to the standard ASSET system and the EDGE/VISTA system enhancement package. The following chart has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE CHART

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Computer Subsystem	Same as K964626.	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 review. Second Ethernet interface allows for communication with systems on the external network.	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.
Image Storage Short Term: Archival:	 Same. Same.	 Magnetic Disk Optical Disk	 Magnetic Disk Optical Disk

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Gradient Subsystem Gradient Coils:	Water-cooled self-shielded gradient system. Phosphorous-bronze RF screen.	Self-shield gradient coil designed for Magnex 0.5T actively shielded magnet. Copper RF screen.	Water-cooled self-shielded gradient system for all performance levels. Stainless ste RF screen.
Max. Gradient Strength	16 mT/m	10 mT/m	16, 20 or 27 mT/m
Max. Slew Rate	25 mT/m/msec	18 mT/m/msec	25, 40, 72 mT/m/msec
Gradient Amps:	150 A RMS, 300 A peak, 400 V	Single high current drive amplifier per axis.	150 A RMS, 300 A peak, 400 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.	Single Channel with fast samplin ADC and additional digital filtering. Three additional receiv channels are available as an option.
RF Amplifiers:	Single frequency 5.0 kW RF amplifier.	Single frequency 2.5 kW RF amplifier.	Single frequency RF amplifiers.
Body Coil	Same as K933835.	57 cm quadrature multi-conductor transmit/receive.	61 cm quadrature multi-conducto transmit/receive coil.

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Head Coil	Same.	Quadrature multi-conductor receive only.	Quadrature multi-conductor receive only.
Receive Only Coil Connection	Same.	All receive only coils plug into single couch RF connector.	All receive only coils plug into single couch RF connector.
Transmit/Receive Box	Same.	Four receive channels in system. (1 standard, 4 optional)	Four receive channels in system. (1 standard, 4 optional)
Magnet Subsystem	Same as K933835.	Actively shielded magnet offered at 0.5 T.	Active Shield Magnets offered at 1.5 T and 1.0 T.
Patient Handling	Same as K933835.	Horizontal motion only, computer controlled patient transport system.	Computer controlled patient transport system with vertical and horizontal motion.
Magnet Facade	Same.	Cylindrical fiberglass enclosure.	Cylindrical fiberglass enclosure.
Power Distribution Subsystem	Same.	Isolation transformer, transient suppression circuitry, and power distribution center all contained in a single cabinet.	Isolation transformer, transient suppression circuitry, and power distribution center all contained i a single cabinet.

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Operating Software	Same as K964626.	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.	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.
Operational Features	Same.	SCAN capabilities include: Pilot positioning on three different reference images. Preloaded anatomical protocol categories. VIEW capabilities include: Multiplanar reconstruction and curvilinear reformatting. FILM capabilities include: ability to set film formats and load print queue directly from Display/Database computer.	SCAN capabilities include: Pilot positioning on three different reference images. Preloaded anatomical protocol categories. VIEW capabilities include: Mult planar reconstruction and curvilinear reformatting. FILM capabilities include: ability to set film formats and load print queue directly from Display/Database computer.

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Standard Imaging Sequences	Same standard imaging sequences with the addition of the AcuScan package.	2DFT: Field Echo, Spin Echo, Multiple Echo, Inversion Recovery and FAST. 3DFT: FAST	2DFT: Field Echo, Spin Echo, Multiple Echo, Inversion Recovery and FAST. 3DFT: FAST
Acquisition and Reconstruction Techniques	Same as K964626.	Main features include: Presaturation, phase conjugate symmetry, TrueRes, TrueSlice, and Geometric Distortion Correction.	Main features include: Presaturation, phase conjugate symmetry, TrueRes and TrueSlice

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Optional Receive Only Coils and Accessories	Same as K933835.	Large Joint Coil Small Joint Coil Volume Neck Coil Quad Spine Coil and Positioner Bilateral TMJ Coil (Linear and Phased Array versions) Bilateral Breast Coil General Purpose Flex Coil C/T/L Phased Array Pelvic Phased Array Flexible Body Coil - Quadrature Quadrature Wrist Coil Quadrature Lower Extremity Coil Coil Combiner	Large Joint Coil Small Joint Coil Volume Neck Coil Quad Spine Coil and Positioner Bilateral TMJ Coil (Linear and Phased Array versions) Bilateral Breast Coil General Purpose Flex Coil C/T/L Phased Array Pelvic Phased Array Flexible Body Coil (Quadrature and Phased Array versions) Quadrature Wrist Coil Quadrature Lower Extremity Coi Coil Combiner Head-Neck Vascular Phased Arr Shoulder Phased Array

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Software Options	Angiography Cardiac Imaging Variable Fast Spin Echo Sequences (2, 4, 8, 16, 32, 48 and 64 echo sequences) Gradient-Recalled and Spin-Echo (GRaSE) Technique Echo Planar Imaging	Angiography Cardiac Imaging Variable Fast Spin Echo Sequences. Gradient-Recalled and Spin-Echo (GRaSE) Technique Echo Planar Imaging	Angiography Cardiac Imaging Variable Fast Spin Echo (2, 4, 8, 16, 32, 48 and 64 echo sequences) Gradient-Recalled and Spin-Echo (GRaSE) Technique Echo Planar Imaging
Time Varying Magnetic Field	Same as K964626.	Not to exceed 20 T/s.	Normal Operating Mode: $dB/dt \leq 40$ T/s First Controlled Operating Mode: $40 \text{ T/s} < dB/dt \leq 60$ T/s
Radiofrequency Absorption	Same as K964626.	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.	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.

ITEM	ASSET APOLLO	Predicate Device ASSET (K933835)	Predicate Device EDGE/VISTA with System Enhancement Package (K964626)
Acoustic Noise Typical Worst Case	71.7 dBA (average) 82.9 dB (peak) 88.8 dBA (average) 96.3 dB (peak)	83.8 dBA (average) 96.8 dB (peak) 98.2 dBA (average) 108.2 dB (peak)	80.6 dBA (average) 93.3 dB (peak) 115.1 dBA (average) 123.8 dB (peak)
Intended Use	Same.	The Picker International ASSET system is intended 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.	The Picker International EDGE / VISTA systems are intended for use as a 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
5500 Avion Park Drive
Highland Heights, Ohio 44143

Re: K971884
ASSET APOLLO (MRI System)
Dated: May 12, 1997
Received: May 22, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

AUG 20 1997

Dear Dr. Keeler:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971884

Device Name: ASSET APOLLO

Indications for Use:

The ASSET APOLLO does not change the existing intended use and indications for the ASSET system as defined below.

The Picker International ASSET system is intended 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971884

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

(Optional Format 1-2-96)