K992412

AUG 17 1999

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

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) Option
Proprietary Name:	*i*Pass Bolus Tracking
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 Contact: Elaine K. Keeler, Ph.D Phone: (440) 473-3000 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 *i*Pass Bolus Tracking option does not change the existing intended use and indications for the Eclipse/Polaris systems as defined below.

The Picker International Eclipse/Polaris 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 Picker *i*Pass Bolus Tracking option improves image quality by coordinating the arrival of the contrast agent with the collection of the data for the center of k-space. The option also includes an auto-voice feature to assist the technician in communicating with the patient.

4. Safety and Effectiveness

The Picker *i*Pass Bolus Tracking option is similar in technological characteristics and intended use to the Picker Eclipse/Polaris system. The following table has been created to demonstrate their substantial equivalence.

Substantial Equivalence Chart

Parameter	*i*Pass Bolus Tracking	Predicate Device - Eclipse / Polaris system (K964626)
Sequence Capabilities / Requirements	Same.	2D RF-FAST sequence, Volume contrast enhanced angio sequence.
Simulate Scan Feature	Same simulate-scan feature is now also used to improve image quality of contrast enhanced angiography scans.	Software uses a simulate-scan feature to improve image quality of single-shot EPI sequences.
ROI Analysis	Software automatically calculates average pixel intensity of the ROI and reports when a 30% increase in this value occurs.	User can draw a ROI and calculate the average pixel intensity. This manual analysis can be repeated on a series of scans to determine when an increase occurs.
Bolus Arrival Time Calculation	Software automatically calculates arrival time based on ROI analysis. Manual override is possible.	User manually determines arrival time based on ROI analysis.
Intercom Capabilities	AutoVoice feature instructs the patient and/or technician during scan.	Technician can communicate with the patient via intercom during scan.
Intended Use and Indications for Use	Same.	The Picker International Eclipse/Polaris 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1999

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
World Headquarters
595 Miner Road
Cleveland, Ohio 44143

Re: K992412
iPass Bolus Tracking MRI System
Dated: July 15, 1999
Received: July 20, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): _____

Device Name: ***i*Pass Bolus Tracking**

Indications for Use:

The *i*Pass Bolus Tracking option does not change the existing intended use and indications for the Eclipse/Polaris systems as defined below.

The Picker International Eclipse/Polaris 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992412

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

(Optional Format 1-2-96)