K974530

FEB 6 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance (MR) Diagnostic Device
Common/Usual Name:	Magnetic Resonance (MR) Device Option
Proprietary Name:	Diffusion-Weighted MR Imaging Package
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 Picker Diffusion-Weighted MR Imaging Package has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility of water molecules in brain tissue affected by acute stroke. Areas of decreased diffusion, as is observed in acute cerebral infarcts, appear as areas of higher image intensity.

Diffusion-weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms.

3. Device Description

The Picker Diffusion-Weighted MR Imaging Package does not change the technological characteristics of the Picker MR Systems. This package consists of echo-planar imaging (EPI) single-shot based sequences which have selectable directionality and either fixed or selectable b-values. The sequences are basically spin-echo sequences which have large gradient pulses or lobes before and after the 180° RF refocusing pulse.

4. Safety and Effectiveness

The Picker Diffusion-Weighted Imaging Package is similar in technological characteristics and intended use to Picker MR systems with Echo-Planar Imaging Capability and the Siemens Diffusion-Weighted Imaging Package. The following table has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE TABLE

Parameter	Diffusion-Weighted MR Imaging Package	Predicate Devices Picker EPI-II Option - K954646 Siemens DWI - K971055
Sequence Description	Same.	Echo-Planar Sequence with large magnetic field gradient pulse before and after the 180° refocusing RF pulse. (K971055)
b-value	Fixed and variable sequences available.	Siemens -- unknown.
Data Correction Calibration	Same.	Semi-automatic prescan process (K954646)
Performance Specifications	Same.	(K954646)
Safety Parameters	Same.	(K954646)

Intended Use / Indications for Use	Same.	The **Siemens Diffusion-Weighted MR Imaging Package** has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility by water molecules in brain tissue affected by acute stroke. Areas of decreased diffusion, as is observed in acute cerebral infarcts, appear as areas of higher image intensity. Diffusion-weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms. (K971055)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 1998

Elaine K. Keeler
Manager, MR Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143

Re: K974530
Diffusion Weighted MRI Package
Dated: November 25, 1997
Received: December 2, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. 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): K974530

Device Name: Diffusion Weighted Imaging Package

Indications for Use:

The Picker Diffusion-Weighted MR Imaging Package has been designed to image the diffusive mobility of water or other proton-containing molecules. One important clinical application is to visualize the apparent loss of mobility of water molecules in brain tissue affected by acute stroke. Areas of decreased diffusion, as is observed in acute cerebral infarcts, appear as areas of higher image intensity.

Diffusion weighted MR pulse sequences are more accurate than conventional MRI pulse sequences in identifying the occurrence of acute stroke during the first 24 hours after onset of symptoms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974530

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

(Optional Format 1-2-96)