

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

K98 4588

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) Accessory
Common/Usual Name:	Magnetic Resonance Imaging (MRI) Coil
Proprietary Name:	Phased Array Flexible Cardiac Coil
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	Not Applicable.

2. Intended Uses

The Phased Array Flexible Cardiac Coil does not change the intended use of the Picker 1.5T Edge Eclipse system.

The 1.5T Edge Eclipse 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 NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, 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 Phased Array Flexible Cardiac Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions:	Heart and associated structures in the thoracic region.
Nuclei Excited:	Hydrogen.

3. Device Description

The Picker Phased Array Flexible Cardiac Coil is enclosed in a flexible, water-resistant fabric housing and is secured to the patient with Velcro straps. This receive-only coil is designed to give improved signal-to-noise, image resolution and image acquisition time over that of the standard body coil.

4. Safety and Effectiveness

The Picker Phased Array Cardiac Coil is substantially equivalent to the Picker Phased Array Flexible Body Coil (K962117) in safety and effectiveness. The following chart has been compiled to demonstrate this equivalence.

Parameter	Phased Array Flexible Cardiac Coil	Predicate Device: Phased Array Flexible Body Coil (K962117)
Compatible MRI Systems	Same.	Picker International 1.5T Systems
Mode of Operation	Same.	Receive-Only
Antenna Configuration	Two anterior loops and two posterior loops.	Co-rotating saddle coils and loops
Tuning/Impedance Matching	Same.	Fixed tuning and matching. Factory set.
Method of Decoupling	Same.	Active PIN diode decoupling
Coil Enclosure	Same.	Flame rated foam and fabric
Number of Receive Channels	Same.	Four
Intended Use	Same.	The 1.5T EDGE 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 NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, 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.

Parameter	Phased Array Flexible Cardiac Coil	Predicate Device: Phased Array Flexible Body Coil (K962117)
Indications for Use	<p>The Flexible Cardiac Coil is indicated for use in the following anatomic regions and with the designated nuclei:</p> <p><i>Anatomic Regions:</i> Heart and associated structures in the thoracic region.</p> <p><i>Nuclei Excited:</i> Hydrogen</p>	<p>The Flexible Body Coil is indicated for use in the following anatomic regions and with the designated nuclei:</p> <p><i>Anatomic Regions:</i> Liver, kidneys, adrenal glands, spleen, bilateral hips and associated abdominopelvic structures.</p> <p><i>Nuclei Excited:</i> Hydrogen.</p>



FEB 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, OH 44143Re: K984588
Phased Array Flexible Cardiac Coil
Dated: December 23, 1998
Received: December 24, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Dr. Keeler:

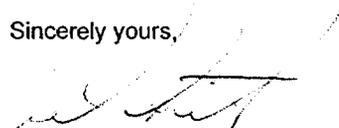
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K984588

Device Name: Phased Array Flexible Cardiac Coil

Indications for Use:

Intended Use

The Phased Array Flexible Cardiac Coil does not change the intended use of the Picker 1.5T EDGE ECLIPSE system.

The 1.5T EDGE ECLIPSE 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 NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, 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.

Indications for Use

The Phased Array Flexible Cardiac Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions: Heart and associated structures in the thoracic region.

Nuclei Excited: Hydrogen.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)