

K 962117

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

AUG 27 1996

**1. General Information**

Classification: Class II  
Magnetic Resonance Imaging (MRI) Accessory

Common/Usual Name: Magnetic Resonance Imaging (MRI) Coil

Proprietary Name: Quadrature and Phased Array Flexible Body Coils

Establishment Registration: Picker International, Inc.  
World Headquarters  
595 Miner Road  
Cleveland, Ohio 44143  
FDA Owner Number: #1580240  
FDA Registration Number: #1525965

Performance Standards: Not Applicable

**2. Intended Uses**

The Quadrature and Phased Array Flexible Body Coils do not change the intended use of the Picker 1.5T EDGE system.

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.

The Quadrature and Phased Array Flexible Body Coils are indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions: Liver, kidneys, adrenal glands, spleen, bilateral hips and associated abdominopelvic structures

Nuclei Excited: Hydrogen

**3. Device Description**

The Picker Flexible Body Coils have either a Quadrature or Phased Array coil architecture enclosed in a flexible package that can be wrapped around the area of interest. The coils are designed to give improved signal-to-noise ratio, image resolution and image acquisition time over that of the standard EDGE body coil.

**4. Safety and Effectiveness**

The Picker Quadrature and Phased Array Flexible Body Coils are substantially equivalent to the MAI Quadrature and Phased Array Abdominal Flex Coils (K954190) in safety and effectiveness. The following chart has been compiled to demonstrate the Flexible Body Coils substantial equivalence to these devices.

<b>Parameter</b>	<b>Quadrature and Phased Array Flexible Body Coil</b>	<b>MAI Quadrature and Phased Array Abdominal Flex Coil (K954190)</b>
Compatible MRI Systems	Picker International 1.5T EDGE	GE 1.5T Signa
Mode of Operation	Receive-Only	Receive-Only
Antenna Configuration	Quadrature: Co-rotating saddle coil pairs  Phased Array: Co-rotating saddle coils and loops	Quadrature: Co-rotating saddle coil pairs  Phased Array: Co-rotating saddle coils and loops
Tuning/Impedance Matching	Fixed tuning and matching. Factory set.	Fixed tuning and matching. Factory set.
Method of Decoupling	Active PIN diode decoupling	Active PIN diode decoupling
Coil Enclosure	Flame rated foam and fabric	Flame rated foam and fabric
Number of Receive Channels	Quadrature: 1 Phased Array: 4	Quadrature: 1 Phased Array: 4

<p>Intended Use</p>	<p>The <b>MAI Quadrature and Phased Array Abdominal Flex Coils</b> are indicated for use as a receive only antenna of RF energy at a specific frequency. The signal received by the coil is dependent upon the MRI parameters (T1 or spin-lattice relaxation time, T2 or spin-spin relaxation time, density of nuclei, flow velocity and chemical shift). The images produced by the imaging coil correspond to the distribution of nuclei exhibiting nuclear magnetic resonance.</p> <p>The Abdominal Flex Coils are intended for use in the following anatomic regions: liver, kidneys, adrenal glands, spleen, bilateral hips and knees, and associated abdominopelvic structures.</p> <p>The <b>Picker Quadrature and Phased Array Flexible Body Coils</b> do not change the intended use of the Picker 1.5T EDGE system. 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.</p> <p>The Flexible Body Coils are indicated for use in the following anatomic regions and with the designated nuclei:</p> <p style="padding-left: 40px;">Anatomic Regions: Liver, kidneys, adrenal glands, spleen, bilateral hips and associated abdominopelvic structures</p> <p style="padding-left: 40px;">Nuclei Excited: Hydrogen</p>
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