

NOV 22 1996

**SUMMARY OF SAFETY AND EFFECTIVENESS**

(As required by 21 CFR 807.92)

K963356

**1. General Information**

Classification: Class II  
Magnetic Resonance Imaging (MRI) Accessory

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

Proprietary Name: Phased Array Shoulder 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 Shoulder Coil does not change the intended use of the Picker 1.5 T EDGE system.

The 1.5 T 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 Phased Array Shoulder Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions: Shoulder and other related joint structures

Nuclei Excited: Hydrogen

### 3. Device Description

The Picker Phased Array Shoulder Coil is a receive-only coil designed to provide imaging of the shoulder and other joint structures. The coil is designed to give improved signal-to-noise ratio (SNR), image resolution and image acquisition time over that of the Body Coil.

### 4. Safety and Effectiveness

The Picker Phased Array Shoulder Coil is substantially equivalent in safety and effectiveness to the MAI Phased Array Shoulder Coil for the GE 1.5 T Signa system. The following chart has been compiled to demonstrate the Shoulder Coil's substantial equivalence to this device.

Parameter	Phased Array Shoulder Coil	Predicate Device MAI Phased Array Shoulder Coil (K945778)
Compatible MRI Systems	Picker International 1.5 T EDGE	GE 1.5 T Signa with Phased Array Hardware Option
Mode of Operation	Same	Receive-Only Array
Antenna Configuration	Same	Multi-channel Array
Tuning/Impedance Matching	Same	Fixed tuning and matching. Factory set.
Method of Decoupling	Same	Passive diode decoupling.
Coil Enclosure	Same	Flame rated thermoplastic enclosure and vinyl pads.
Number of Receive Channels	Same	Four

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

Anatomic Regions: Shoulder and other related joint structures

Nuclei Excited: Hydrogen

Parameter	Phased Array Shoulder Coil	Predicate Device MAI Phased Array Shoulder Coil (K945778)
Intended Use	<p>The <b>MAI Phased Array Shoulder Coil</b> is indicated for use as a receive only antenna of RF energy at a specific frequency. The signal received by the coils is dependent upon 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 MAI Phased Array Shoulder Coil is indicated for use in the following anatomic regions: shoulder and other related joint structures.</p> <p>The <b>Phased Array Shoulder Coil</b> does not change the intended use of the Picker 1.5 T EDGE system. The 1.5 T 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 Phased Array Shoulder Coil is indicated for use in the following anatomic regions and with the designated nuclei:</p> <p style="text-align: right;">Anatomic Regions:   Shoulder and other related joint structures.</p> <p style="text-align: right;">Nuclei Excited:        Hydrogen</p>	