

**JUL - 5 1996**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**K960497**

**1. General Information**

**Classification:** Class II  
Magnetic Resonance (MR) Imaging System

**Common/Usual Name:** MRI Receive-Only Coil

**Proprietary Name:** Flexible Phased Array Spine Coil

**Establishment Registration:** **Manufacturer:**  
Picker Nordstar, Inc.  
P.O. Box 33  
FIN-0051 Helsinki, FINLAND  
**Phone:** +358-0-394 127  
**Fax:** +358-0-146 2811  
FDA Facility Registration #9680194

**United States Representative:**  
Picker International, Inc.  
595 Miner Road  
Cleveland, OH 44143  
FDA Owner Number: #1580240

**Performance Standards** No applicable performance standards have been used under section 514 of the Food, Drug and Cosmetic Act.

**2. Intended Uses**

The Flexible Phased Array Spine Coil is designed to provide coverage of the thoracic and lumbar spinal regions of the body. The indications for use are the same as for standard MR imaging.

**3. Device Description**

The Flexible Phased Array Spine Coil is a phased array coil package consisting of a solenoid and a saddle coil element. All elements and associated circuitry are enclosed in a flexible vinyl enclosure.

The patient is wrapped with the coil allowing for ease of patient positioning. The coil has a fixed circumference and attaches by snapping the ends together.

4. Safety and Effectiveness

**SUBSTANTIAL EQUIVALENCE CHART**

<b>PARAMETER</b>	<b>FLEXIBLE SPINE COIL</b>	<b>PREDICATE</b>
Coil Enclosure Material	Vinyl fabric	Same as material uses in Picker Extended Coverage Head Coil (K893619)
Coil Design	Two-channel receive-only phased array coil	Outlook Body Coil is a receive-only phased array coil (K945827)
Decoupling	Active PIN diode decoupling	Same as Body Coil for Outlook (K945827)
Formation of Resonant Loops	The length of the cable and its stiffness does not permit looping.	N/A
Potential for RF burns	Does not transmit RF power.  Coil elements and associated circuitry encased in non-conductive material.  Decoupling isolates the coil elements from transmitted RF.	Same as other Outlook Coils (K945827)
Radio Frequency Absorption	Power deposition during imaging is limited by the SAR algorithm.	Algorithm used on Outlook system (K945827)
Intended Use	Thoracic and Lumbar spine regions.	Body Coil for Outlook (K945827)
Indications for Use	Same as for standard MR imaging.	Body Coil for Outlook (K945827)