

SUMMARY OF SAFETY AND EFFECTIVENESS

K964820

FEB 28 1997

- 1. Device Name : Magnetic Resonance Imaging Accessory
- 2. Proprietary Name : Maxim 7000 Quadrature Extremity Coil
- 3. Classification : Class II
- 4. Establishment Registration #: 1529041
- 5. Manufacture Facility Location: USA Instruments, Inc., 675-B Alpha Drive, Highland Heights, Ohio 44143, USA Telephone: 216-442-5920; Fax: 216-442-5919.
- 6. Performance Standard: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
- 7. Intended Use: The Quadrature Extremity Coil is a receive-only quadrature RF coil, used for obtaining diagnostic images of the elbow anatomy in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Quadrature Extremity Coil is designed for use with GE Signa (1.5 Tesla) MRI scanner manufactured by GE Medical Systems.
- 8. Device Description: The Quadrature Extremity Coil consists of two volume RF coil elements in a quadrature design. The elements and circuitry are enclosed in a durable covering made of vinyl naughahyde which is fire rated.

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9. Safety and Effectiveness

<b>Parameter</b>	<b>Quadrature Elbow Coil</b>	<b>Predicate</b>
<b>Intended Use</b>	<b>Elbow Imaging Applications</b>	<b>General Purpose Flex Coil (K944469) marketed by Picker International</b>
<b>Indications for Use</b>	<b>Identical to routine MRI imaging</b>	<b>General Purpose Flex Coil (K944469) marketed by Picker International</b>
<b>Coil Enclosure Material</b>	<b>Vinyl Fabric</b>	<b>Flexible Spine Coil (K960497) marketed by Picker International</b>
<b>Coil Design</b>	<b>Quadrature design</b>	<b>Profile 7000 C-spine Coil (K943440) marketed by US Asia Instruments. Inc.</b>
<b>Decoupling</b>	<b>Switching Diode decoupling</b>	<b>Profile 7000 C-spine Coil (K943440) marketed by US Asia Instruments. Inc.</b>
<b>Prevention of RF Burns</b>	<p><b>Does not transmit RF Power</b></p> <p>Decoupling isolates the coil elements from RF during RF transmission</p> <p>Coil elements and circuitry is enclosed in a non-conductive material.</p>	<b>Profile 7000 C-spine Coil (K943440) marketed by US Asia Instruments. Inc.</b>
<b>Radio Frequency Absorption</b>	<b>Coil is a receive only coil and does not transmit RF</b>	<b>Profile 7000 C-spine Coil (K943440) marketed by US Asia Instruments. Inc.</b>
<b>Formation of Resonant Loop</b>	<p>Decoupling isolates the coil elements from RF during RF transmission</p> <p>Length of cable and stiffness does not permit looping</p>	<b>Profile 7000 C-spine Coil (K943440) marketed by US Asia Instruments. Inc.</b>