

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

FEB 11 1997

K964678

1. General Information

Classification: Class II
Magnetic Resonance (MR) Imaging System

Common/Usual Name: MRI Receive-Only Coil

Proprietary Name: Phased Array Neck Coil

Establishment Registration

Manufacturer:

Picker Nordstar, Inc.
P.O. Box 33
FIN-00511 Helsinki, FINLAND
Phone: +358-9-394 127
Fax: +358-9-146 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 issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Phased Array Neck Coil is designed to provide coverage of the neck, from the cerebellum to the upper thoracic spine region. The intended use is the same as for standard MR imaging.

3. Device Description

The Phased Array Neck Coil is a phased array coil consisting of two coil elements. All elements and associated circuitry are covered by ABS and polycarbonate enclosures.

4. Safety and Effectiveness

SUBSTANTIAL EQUIVALENCE CHART

PARAMETER	PHASED ARRAY NECK COIL	PREDICATE DEVICE Vascular Head Coil (K945827) & Multipurpose size M Coil (K925987)
Enclosure Material	ABS and Polycarbonate	Polyurethane
Coil Design	Same	Two-channel receive-only phased array coil.
Decoupling	Same	Active PIN diode decoupling
Formation of Resonant Loops	Same	The length of the cable and its stiffness does not permit looping.
Potential for RF burns	Same Same Same	Does not transmit RF power. Coil elements and associated circuitry encased in non-conductive material. Decoupling isolates the coil elements from transmitted RF.
Radio Frequency Absorption	Same	Power deposition during imaging is limited by the SAR algorithm.
Indications for Use	Neck, from the cerebellum to the upper thoracic spine region.	Head and cervical spine.

Intended Use	Same	<p>The Picker International, Inc. Outlook system which is manufactured by Picker Nordstar, Inc. is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, MR images yield useful diagnostic information.</p>
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