

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

1. General Information

Classification: Class II
Magnetic Resonance Imaging (MRI) Accessory

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

Proprietary Name: Outlook Large Phased Array Neck 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 Picker Outlook 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 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, these images yield information that can be useful in the determination of a diagnosis.

The Large Phased Array Neck Coil is indicated for use in providing coverage of the neck, from the cerebellum to the upper thoracic spine region.

Anatomic Regions: Neck

Nuclei Excited: Hydrogen

3. Device Description

The Large Phased Array Neck Coil is a receive-only coil for the 0.23T Outlook system, and is optimized to image the cervical spine. The sensitive region of the coil covers the base of the cerebellum to the third thoracic vertebra for greater than 98% of patients.

4. Safety and Effectiveness

The Picker Large Phased Array Neck Coil is substantially equivalent in safety and effectiveness to the USA Instruments (USAI) Quadrature Volume Neck Coil and the Picker Phased Array Neck Coil. The following chart has been compiled to demonstrate the substantial equivalence of these devices.

Parameter	Large Phased Array Neck Coil	Predicate Device Picker - Outlook Neck Coil (K964678) USAI - Profile 7000 Neck Coil (K964531)
Compatibility	Picker 0.23T Outlook system	Hitachi 1.5T MRH-1500 system (See K964531)
Enclosure Material	Same.	Royalite R59 ABS/PVC alloy (See K964531)
Coil Design	Two-channel receive-only phased array coil.	Two-channel receive-only quadrature coil (See K964531).
Decoupling	Same.	Switching Diode decoupling. (See K964531)
Formation of Resonant Loops	Same.	Length of cable and stiffness does not permit looping (See K964531 or K964678)
Potential for RF burns	Same.	Limited by the following: 1) Does not transmit RF power 2) Coil elements and circuitry encased in non-conductive material. 3) Decoupling isolates the coil elements from transmitted RF. (See K964531 or K964678)
Radio Frequency Absorption	Same.	Coil is receive-only and does not transmit RF power. Power deposition during imaging is limited by the system SAR algorithm. (See K964531 or K964678)
Tuning Scheme	Same.	Automatically tuned for each patient. (See K964678)

Parameter	Large Phased Array Neck Coil	Predicate Device Picker - Outlook Neck Coil (K964678) USAI - Profile 7000 Neck Coil (K964531)
Indications for Use	Same.	<p>The Phased Array Neck Coil is indicated for use in providing coverage of the neck, from the cerebellum to the upper thoracic spine region.</p> <p>Anatomic Regions: Neck Nuclei Excited: Hydrogen (See K964678)</p>
Intended Use	Same.	<p>The Picker Outlook 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 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, these images yield information that can be useful in the determination of a diagnosis. (See K964678)</p>



JUL 31 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Cleveland, OH 44143Re: K981959
Outlook Large Phased Array Neck Coil
Dated: June 2, 1998
Received: June 4, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Dr. Keeler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981959

Device Name: Large Phased Array Neck Coil

Indications for Use:

The Picker Outlook 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 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, these images yield information that can be useful in the determination of a diagnosis.

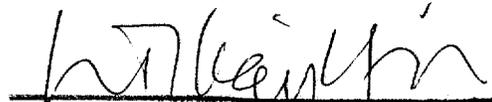
The Large Phased Array Neck Coil is indicated for use in providing coverage of the neck, from the cerebellum to the upper thoracic spine region.

Anatomic Regions: Neck

Nuclei Excited: Hydrogen

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981959

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)