

K97 4844

MAR 10 1998

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

**1. General Information**

Classification: Class II  
Magnetic Resonance (MR) Imaging System

Common/Usual Name: Magnetic Resonance (MR) Imaging Option

Proprietary Name: Outlook System Enhancement Package

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.  
World Headquarters  
595 Miner Road  
Highland Heights, Ohio 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 system enhancement package does not change the existing indications for the standard Outlook system as defined below.

The Outlook system is indicated 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.

**3. Device Description**

The Outlook System Enhancement Package includes changes in the computer subsystem, magnet subsystem, gradient subsystem, RF subsystem, patient handling subsystem, magnet enclosure and the power distribution subsystem. The package also includes additional imaging sequences and acquisition/reconstruction techniques. However, the basic features of the operating software are unchanged.

**4. Safety and Effectiveness**

Outlook systems with the System Enhancement Package are similar in technological characteristics and intended use to the standard Outlook system and the EDGE/VISTA System Enhancement Package. The following chart has been created to demonstrate their substantial equivalence.

**SUBSTANTIAL EQUIVALENCE CHART**

Item	Outlook System Enhancement Package	Predicate Devices Standard Outlook (K945827) Edge/Vista System Enhancement (K964626)
Computer subsystem	<p>Same display/database computer system with some additional options.</p> <p>Ethernet communication system</p> <p>Scan/reconstruction hardware:</p> <ul style="list-style-type: none"> <li>• single processor for reconstruction</li> <li>• additional hard disk for buffering image raw data</li> </ul> <p>DICOM 3.0 compliant</p>	<p>Display/database computer system:</p> <ul style="list-style-type: none"> <li>• workstation</li> <li>• single monitor</li> <li>• movable keyboard and mouse</li> <li>• magnetic disk storage</li> <li>• optical disk storage</li> <li>• CD-ROM</li> </ul> <p>Ethernet communication system</p> <p>Scan/reconstruction hardware:</p> <ul style="list-style-type: none"> <li>• 16 parallel processors for reconstruction</li> </ul> <p>(See K945827)</p> <p>DICOM 3.0 compliant. (See K964626)</p>
Magnet subsystem	<ul style="list-style-type: none"> <li>• Iron C-arm magnet</li> <li>• Ramp up time: 6 minutes</li> <li>• Increased stability of magnetic field</li> </ul>	<ul style="list-style-type: none"> <li>• Iron C-arm magnet</li> <li>• Ramp up time: 10 minutes</li> </ul> <p>(See K945827)</p>

Item	Outlook System Enhancement Package	Predicate Devices Standard Outlook (K945827) Edge/Vista System Enhancement (K964626)
Gradient subsystem	Increased gradient performance with an active shielded design.	Gradient performance level of 12 mT/m and 20 T/m/s with a shielded design. (See K945827)
RF subsystem • RF amplifier max average power  • Receive bandwidth	<ul style="list-style-type: none"> <li>• 500 W</li> <li>• <math>\pm 100</math> kHz</li> </ul>	<ul style="list-style-type: none"> <li>• 250 W</li> <li>• <math>\pm 50</math> kHz (See K945827)</li> </ul>
Patient Handling subsystem	<ul style="list-style-type: none"> <li>• Modified couch movable in two directions</li> <li>• Laser positioning</li> </ul>	<ul style="list-style-type: none"> <li>• Couch movable in two directions</li> <li>• Laser positioning (See K945827)</li> </ul>
Magnet Enclosure	Fiberglass enclosure re-designed to accommodate patient handling subsystem.	Fiberglass enclosure. (See K945827)
Power Distribution subsystem	Same with the addition of line voltage monitoring circuitry.	Isolation transformer, transient suppression circuitry, power distribution center all contained in a single cabinet. (See K945827)
Operating software	Same.	Windows NT based Graphical User Interface and scan / reconstruction software with multi-tasking capability. (See K945827)
Imaging Sequences	Same with enhancements to Inversion Recovery and Fast Spin Echo sequences.	Standard: Field Echo, Spin Echo, Inversion Recovery, Dual Echo, and CBASS.  Optional: Fast Spin Echo and Angiography. (See K945827)

Item	Outlook System Enhancement Package	Predicate Devices Standard Outlook (K945827) Edge/Vista System Enhancement (K964626)
Acquisition and Reconstruction Techniques	Same with addition of: <ul style="list-style-type: none"> <li>• Read Conjugate Symmetry</li> <li>• TrueRes</li> <li>• Keyhole</li> </ul>	Main features include: <ul style="list-style-type: none"> <li>• Presaturation</li> <li>• MAST</li> <li>• Optimized Data Acquisition</li> <li>• Phase Conjugate Symmetry</li> <li>• No Phase Wrap-Around</li> <li>• No Slice Wrap-Around</li> <li>• Dynamic Imaging</li> <li>• Cardiac gating</li> <li>• Optimized Bandwidth</li> <li>• Turbo Multislice</li> </ul> (See K945827)
Receive Only Coils	<ul style="list-style-type: none"> <li>• Head</li> <li>• Brain</li> <li>• Vascular Head and Neck</li> <li>• Neck</li> <li>• Body/Spine</li> <li>• Flexible Spine</li> <li>• Multipurpose</li> <li>• Extremity</li> <li>• Small Joints</li> </ul>	<ul style="list-style-type: none"> <li>• Head</li> <li>• Vascular Head and Neck</li> <li>• Neck</li> <li>• Body</li> <li>• Spine</li> <li>• Flexible Spine</li> <li>• Multipurpose</li> <li>• Extremity</li> </ul> (See K945827)
Static Magnetic Field	Same.	0.23 T (See K945827)
Time Varying Magnetic Field	Same.	Normal operating mode: $dB/dt \leq 40 \text{ T/s}$  First level controlled operating mode: $dB/dt \leq 60 \text{ T/s}$ (See K964626)
Radiofrequency Absorption	Same.	Normal operating mode: Limited to a maximum level of 1.2 W/kg.  First level controlled operating mode: Limited to a maximum level of 3.2 W/kg. (See K964626)
Acoustic Noise	Same.	A-weighted average value < 85 dBA. (See K945827)



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Duane C. Praschan  
Manager, MR Regulatory Affairs and  
Clinical Testing  
Pickef International, Inc.  
595 Miner Road  
Highland Heights, Ohio 44143Re: K974844  
Outlook System Enhancement Package  
Dated: December 22, 1997  
Received: December 24, 1997  
Regulatory class: II  
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Praschan:

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): K974844

Device Name: Outlook System Enhancement Package

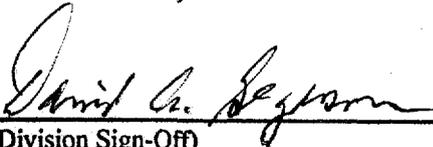
**Indications for Use:**

The system enhancement package does not change the existing indications for the standard Outlook system as defined below.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K974844

Prescription Use   
(Per 21 CFR 801.109)

OR

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