

DEC 21 1998

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

1. General Information

Classification: Class II
Magnetic Resonance Imaging (MRI) System

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

Proprietary Name: MR Guided Procedures (MRGP) Basic Package

Establishment Registration: *Manufacturer:*
Picker Nordstar, Inc.
Ayritie 4, Vantaa
FIN-01510 Vantaa Finland
FDA Facility Registration: #9680194

United States Representative:
Picker International, Inc.
World Headquarters
595 Miner Road
Highland Heights, Ohio 44143
FDA Owner Number: #1580240
FDA Registration Number: #1525965

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

2. Intended Uses

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.

The MRGP Basic Package is designed to support and guide diagnostic interventional procedures, such as needle biopsies and drainages.

3. Device Description

The MRGP Basic Package is an optional hardware package for the Outlook and Outlook Proview systems. The package includes a foot pedal for starting scans from inside the scan room, kneeling pads for the physician, an MR compatible procedure light, a multipurpose coil with disposable protective coil coverings, and either an in-room LCD display or an in-room Large (36") Screen display. The package uses the standard software and sequences available with the Outlook and Outlook Proview systems.

4. Safety and Effectiveness

The Picker MRGP Basic Package is substantially equivalent to the Siemens Magnetom Open MR Guided Procedures Package and the Picker Outlook System Enhancement Package. The following chart has been compiled to demonstrate this equivalence.

Substantial Equivalence Chart

Parameter	MR Guided Procedures (MRGP) Basic Package	Outlook System Enhancement Package (Proview) - K974844	Siemens MR Guided Procedure Package - K955389
System Compatibility	0.23T Outlook, 0.23T Outlook Proview	Not Applicable.	0.2T Magnetom Open
Magnet Homogeneity	Same.	Same.	± 5 ppm @ 40 cm DSV (FWHM)
Magnet ramp time	Same as K974844.	6 minutes	Approx. 30 minutes
Gradient Design	Same as K974844.	<ul style="list-style-type: none"> ▪ Water-cooled gradient coils ▪ Peak strength - 16 mT/m ▪ Slew rate - 25 mT/m/ms 	<ul style="list-style-type: none"> ▪ Water-cooled gradient coils ▪ Peak strength - 15 mT/m ▪ Slew rate - <17 mT/m/ms
Patient accessibility	Same as K974844.	<ul style="list-style-type: none"> ▪ Gap (couch-pole) - 44 cm ▪ Access from three sides 	<ul style="list-style-type: none"> ▪ Gap (couch-pole) - 40 cm ▪ Access from three sides
Patient couch	Same.	Same.	Detachable mobile couch.
Patient positioning	Same.	Same.	Laser localizer for positioning
Sequence type	Same as K974844.	2D/3D Gradient echo, FSE, Single-shot FSE.	Rapid gradient echo imaging, FIS
Sequence capabilities	Same as K974844.	Dynamic imaging with auto start and keyhole imaging capabilities. Typical reconstruction of 200 ms per image.	Continuous imaging with automatic display. Typical reconstruction of less than 600 ms per image.
Sequence resolution	Same as K974844.	<ul style="list-style-type: none"> ▪ FOV- 4 to 40 cm ▪ Slice thickness - <ul style="list-style-type: none"> · 2D: 1-100mm (0.1mm steps) · 3D: 0.4-100mm (0.1mm steps) ▪ Matrix- up to 512 	<ul style="list-style-type: none"> ▪ FOV - 4 to 40 cm (2D), 12 to 40 cm (3D) ▪ Slice thickness - <ul style="list-style-type: none"> · 2D: 2-60mm (1 mm steps) · 3D: ?? ▪ Matrix- 128, 256, 512 (2D or 3D)

Parameter	MR Guided Procedures (MRGP) Basic Package	Outlook System Enhancement Package (Proview) - K974844	Siemens MR Guided Procedure Package - K955389
In-room display and scan control	Two types of in-room displays available- 1) LCD same as K974844, 2) Large (36") Screen display with 1024x768 resolution. Foot pedal also provided to start scans.	In-room LCD display with 1024x768 resolution.	In-room LCD display with 1024x1280 resolution. Foot pedal also provided to start scans.
RF coils	Same coils as K974844. Non-sterile protective coverings provided to prevent degradation of performance due to fluid ingress.	Belt shaped Multipurpose coils with circumferences ranging from 40 to 136 cm.	Belt shaped Multipurpose coil with a circumference 109 cm.
Sterile drapes	User instructed to cover magnet poles with standard sterile drapes. Drapes not provided with package.	None.	Reusable cover provided for magnet poles. Can be steam sterilized.
Physician Ergonomics	Set of kneeling cushions	None.	Chair
Procedure Lighting	Adjustable MR compatible light on movable stand.	None.	Flexible fiber-optic lamp, attached on a flexible arm at the magnet cover for sterile handling
Indications for Use	The MRGP Basic Package is designed to support and guide diagnostic interventional procedures, such as needle biopsies and drainages.	Standard MR imaging indications for use. No interventional indications.	The MR-guided procedure package is designed to support diagnostic interventional needle biopsies and drainages.



DEC 21 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, OH 44143

Re: K983342
MR Guided Procedures (MRGP) Basic Package
Dated: September 21, 1998
Received: September 23, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LHN

Dear Dr. Keeler:

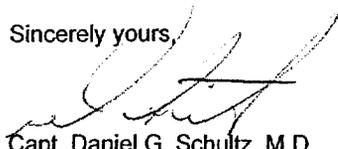
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (Pre-market 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,



Capt. Daniel G. Schultz, M.D.
Acting 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): K983342

Device Name: **Magnetic Resonance Guided Procedures (MRGP) Basic Package**

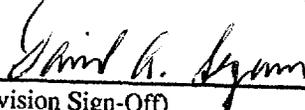
Indications for Use:

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The MRGP Basic Package is designed to support and guide diagnostic interventional procedures, such as needle biopsies and drainages.

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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 K983342

Prescription Use
(Per 21 CFR 801.109)

OR

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