AUG 23 1999

K991943

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:	MRGP Optical Tracking Unit
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 Contact: Elaine K. Keeler, Ph.D. Phone: (440) 473-3000 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 Optical Tracking Unit is designed to support and guide diagnostic and therapeutic interventional procedures, such as needle biopsies and drainages.

3. Device Description

The main features in the Optical Tracking Unit include: 1) infrared digitizer hardware; 2) specialized tools and tracking devices for procedures; 3) software that guides the imaging plane based on information from the digitizer; 4) software utilities that allow for slice reformatting of 3D image sets and 5) MRGP graphical overlays for planning and intraoperative use.

This guidance mechanism shortens the time needed to find the correct imaging plane, and is useful in cases that require a difficult trajectory (i.e. double oblique imaging planes).

4. Safety and Effectiveness

The following substantial equivalence chart has been compiled to demonstrate the equivalence of the MRGP Optical Tracking Unit described in this submission with the Picker MRGP Basic Package (K983342) and the Picker ViewPoint Passive Tool Option (K990868).

Substantial Equivalence Chart

Parameter	MRGP Optical Tracking Unit	Predicate Devices
System Compatibility	Same.	0.23T Outlook, 0.23T Outlook Proview (See K983342)
Software	Special MRGP Software for the Outlook.	Standard Outlook Software. (See K983342)
Imaging Plane Selection	Optically Guided.	Manual. (See K983342)
Sequence type	Same.	2D/3D Gradient echo, FSE, Single-shot FSE. (See K983342)
Sequence capabilities	Same.	Dynamic imaging with auto start and keyhole imaging capabilities. Typical reconstruction of 200 ms per image. (See K983342)
Sequence resolution	Same.	· FOV- 4 to 40 cm · Slice thickness- 2D: 1-100mm (0.1mm steps) 3D: 0.4-100mm (0.1mm steps) · Matrix- up to 512 (See K983342)

Parameter	MRGP Optical Tracking Unit	Predicate Devices
Type of Digitizer	Same.	Infrared signals emitted from the Position Sensor Assembly (PSA) are reflected off reflective markers mounted on the tool. The reflected signal is detected by the PSA with two optical detectors. (See K990868)
Max. Digitizer Rate	Same.	30 Hz for one or two tools; for three tools, the rate is 30 Hz for one of the tools and 15 Hz for the other two. (See K990868)
Active Digitizer Volume	Same.	Silo shape, with 1 meter diameter and 1 meter length. (See K990868)
Type of Sterilization	Same.	Tool bodies are steam sterilized and the reflective spheres are sterilized with ETO. (See K990868)
Material Composition of tool bodies	Polyethermide and Polyphenylsulfone	Aluminum, titanium or stainless steel (See K990868)
Indications for Use	The MRGP Optical Tracking Unit is designed to support and guide diagnostic and therapeutic interventional procedures, such as needle biopsies and drainages.	The MRGP Basic Package is designed to support and guide diagnostic interventional procedures, such as needle biopsies and drainages. (See K983342)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 1999

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

Re: K991943
MRGP Optical Tracking Unit
(Interventional MRI Accessory)
Dated: June 7, 1999
Received: June 9, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

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 (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,

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): K991943

Device Name: MRGP Optical Tracking Unit

Indications for Use:

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(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 K991943

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)