

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

1. General Information

Classification: Class II
Magnetic Resonance Imaging (MRI) Option

Common/Usual Name: Magnetic Resonance Spectroscopy Option

Proprietary Name: MR Spectroscopy Package

Establishment Registration: 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 and Indications for Use

The Picker MR Spectroscopy Package is intended for use as a non-invasive diagnostic device that provides information based on relative concentrations of metabolites in body tissues. This NMR data in the form of spectra or spectral images reflect the NMR properties of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and chemical shift. When interpreted by a trained medical practitioner, these spectral data provide information that can be useful in making a diagnosis.

This package is indicated for use as follows:

Anatomical region: Head, whole body
Nuclei Excited: ^1H

3. Device Description

Picker's MR Spectroscopy Package described in this submission is a proton (^1H) spectroscopy software option. The package includes both capabilities for single voxel proton (SVP) spectroscopy and chemical shift imaging (CSI). These techniques provide a non-invasive method for analyzing metabolite concentrations in the brain and throughout

the body. The MR Spectroscopy Package does not include any additional risks to the patient other than those for standard MR imaging.

4. Safety and Effectiveness

The Picker MR Spectroscopy Package is similar in technological characteristics and intended use to the Siemens Clinical Proton Spectroscopy Package and the GE Probe/SV Option. The following table has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE TABLE

| Parameter | Picker MR Spectroscopy Option | Predicate Devices: GE Probe (K930265), Siemens (K951650) |
|--------------------------|---|--|
| Nucleus | Same. | Proton. (Both predicates) |
| Type of Spectroscopy | Same. | Single Voxel and Chemical Shift Imaging. (See K951650) |
| Spectroscopic Hardware | Same. | Phantom for QA. (See K951650) |
| Shimming Technique | Same. | Automated. (See K930265) |
| Solvent Suppression | Automated with the choice of MOIST, MOIST2, FATFREE and DUALSAT. | Automated CHESS. (See K930265) |
| Localization Techniques | Same. | STEAM and PRESS. (See K930265) |
| Voxel positioning | Graphical positioning. | Alphanumerical or graphical positioning. (Both predicates) |
| Minimum voxel size | 5 x 5 x 5 mm ³ . | 10 x 10 x 10 mm ³ . (See K951650) |
| Minimum TE | STEAM – 20ms, PRESS – 35 ms. | STEAM – 10ms, PRESS – 35ms. (See K930265) |
| Typical TR Range | 1.5 – 3 sec. | 1.5 – 6 sec. (See K930265) |
| Acquisition Time | Approximately 3 – 7 minutes. | Approximately 10 minutes. (See K930265) |
| Post-processing features | Phase correction, filtering, data zeroing, retrospective voxel boundary shifting, FFT, baseline correction, peak fitting and analysis, chemical shift assignment, variable smoothing and differentiation. | Zero filling, water reference processing, FID shifting, baseline correction, phase correction, FFT, apodization, Curve fitting, peak information display, spectrum labeling. (See K951650) |
| Key Metabolites | NAA, Cr, Cho, mI, Glx and Lac. | NAA, Cr/PCr, Cho, lipids and some other metabolites only at short TEs. (See K951650) |

| Parameter | Picker MR Spectroscopy Option | Predicate Devices: GE Probe (K930265), Siemens (K951650) |
|----------------------|--|---|
| Data display options | Same. | Spectra, results of fit, images showing metabolite distributions or ratios. (See K951650) |
| Output type | Archived to database, film, post-script printer. | Archived in database, Windows bitmap format, laser camera, standard paper laser printer, digital printer. (See K951650) |
| Indications for use | Head, whole body. | Brain and any anatomy containing little or no fat. (See K930265) |
| Intended Use | <p>The Picker MR Spectroscopy Package is intended for use as a non-invasive diagnostic device that provides information based on relative concentrations of metabolites in body tissues. This NMR data in the form of spectra or spectral images reflect the NMR properties of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and chemical shift. When interpreted by a trained medical practitioner, these spectral data provide information that can be useful in making a diagnosis.</p> | <p>The GE Signa Advantage MR diagnostic system is indicated for use as a diagnostic medical device that produces computer processed, localized spectra that display the internal biochemical characteristics of the human body. Other parameters derived from the spectra may also be displayed. The spectra reflect the frequency distribution of several biologically relevant nuclei exhibiting nuclear magnetic resonance (NMR). The NMR properties that determine the spectral appearance are nuclear density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), chemical shift in resonant frequency, and fluid flow. When interpreted by a trained specialist, these spectra provide information that may be useful in the determination of a diagnosis. (See K930265)</p> |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 19 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

RE: K991568
Magnetic Resonance Spectroscopy Package
Dated: April 30, 1999
Received: May 5, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNI

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): K991568

Device Name: MR Spectroscopy Package

Indications for Use:

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This package is indicated for use as follows:

Anatomical region: Head, whole body
Nuclei Excited: ¹H

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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 K991508

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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