K030317

MAR 2 5 2003

4.0 Attachment 2: 510(K) Summary of Safety and Effectiveness

Device Name:	Model 1300GE-64 – Pediatric Positioner
Applicability:	Compatible with GE Signa 1.5T MRI Systems
Reason for 510(k):	New device
Classification Name:	Magnetic Resonance Diagnostic Device
Device Classification Panel:	Radiology
Device Classification Number:	892.1000
Product Code:	90MOS
Common Name:	MRI Accessory
Proprietary Name:	Model 1300GE-64 – Pediatric Positioner
Establishment Registration Number:	2134565
Address of MFG Facility:	Midwest RF, LLC 535 Norton Drive Hartland, WI 53029
Classification:	Class II
Intended Uses:	
Diagnostic Uses:	2D, 3D imaging, proton density, T1 and T2 weighted imaging, 2D, 3D time of flight, phase contrast imaging. Proton spectroscopy.
Anatomic Regions:	Pediatric head, body and extremities.

Standards:

Performance Standards:	None established under Section 514

Voluntary Safety Standards:

UL-94	Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
IEC-60601-1	International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC-60601-2-33	International Electrotechnical Commission, Part 2: particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health (CDRH) released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. Due to considerable technological advances in MRDDs, CDRH issued an updated guidance document on November 14, 1998. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The GE Signa 1.5T MRI System, operated with the Midwest RF Pediatric Positioner, is substantially equivalent to the GE Signa 1.5T MRI System operated with the legally market predicated devices listed in Attachment 8 of this PMN, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

Safety Parameters

Maximum Static Magnetic Field:	No change
Rate of Magnetic Field Strength Change:	No change

RF Power Deposition:	No change when used in accordance with operator instructions
Acoustic Noise Levels:	No change
Biocompatibility:	No change

Imaging Performance Parameters

Specification Volume:	No change
Signal-to-Noise Ratio:	No change (within measurement error)
Image Uniformity:	No change (within measurement error)
Geometric Distortion:	No change
Slice Thickness and Gap:	No change
High Contrast Spatial Resolution:	No change

General Safety and Effectiveness Concerns

The device contains detailed instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing.

Substantial Equivalence Summary

The GE Signa 1.5T MRI System, operated with the Midwest RF Pediatric Positioner addressed in this PMN, has the same intended use and technological characteristics as the GE Signa 1.5T MRI System operated with the legally market predicated devices. The use of this device does not alter the GE Signa 1.5T MRI System safety parameter specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Mr. Helmut Keidl
CEO
Midwest R.F., LLC
535 Norton Drive
HARTLAND WI 53209

Re: K030317
Trade/Device Name: Model 1300GE-64 Pediatric Positioner
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: January 28, 2003
Received: January 30, 2003

Dear Mr. Keidl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 Attachment 3: Statement of Indication for Use

510(K) Number (if known): K030317

Device Name: **Pediatric Positioner, Model # 1300GE-64**

Indications For Use:

Magnetic Resonance Imaging (MRI), Magnetic Resonance Angiography (MRA) and Proton Spectroscopy of the pediatric head, body and extremities. This device is used in conjunction with a General Electric 1.5 Tesla MRI System. Proton Spectroscopy is used in conjunction with the PROBE (Proton Brain Exam) option.

(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_____

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-the Counter Use _____ (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030317