K061730

Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

JUL 28 2006

June 30, 2006

Special 510(k) Summary - Device Modification

Submitter Information:

Company FONAR Corporation
Registration Number 2432211
110 Marcus Drive, Melville, New York 11747-4292

Contact: Luciano Bonanni Executive Vice President
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Device Designation:

Trade Name: Indomitable Magnetic Resonance Imaging Scanner Accessory
Common Name: Magnetic Resonance Imaging Scanner (MRI Scanner)
Classification: System, Nuclear Magnetic Resonance Imaging (NMR/MRI)
Product Code: LNH Class: 2 Tier: 2
C.F.R. Section 892.1000 Classification Panel: Radiology

Reason for Submission: Change in operational limits for gradient subsystem.

FONAR Corporation has modified the existing control limits for the Indomitable scanner gradient subsystem to allow the maximum gradient current to increase by 50 percent, with a corresponding increase in the maximum slew rate for the gradient waveforms. All other subsystems remain essentially unchanged from their previously approved (K002490) state.

Device Modifications

This modified gradient subsystem follows the same basic design principles as our previously approved gradient systems. It functions on the same basic operating and physical principles as the predicate device, the Indomitable gradient system (K002490). It is constructed with the same manufacturing materials, and is fabricated in the same fashion to the previously approved gradients.

The primary differences of this modification to the gradient subsystem are the software limits for maximum gradient current value and the increased slew rate that accompanies the changed current value. It is, in summary, a significant equivalent of FONAR's currently approved predicate device.

Description of Device

Gradient Subsystem

The gradients provide the ability of the system to accurately determine spatial location within the imaging volume. They are also used to help establish control of other imaging factors such as slice thickness and field-of-view. The gradients used on the Indomitable magnet, which are unchanged in this submission have the same overall diameter, and are still comprised of the same three quadrupolar (linear) gradients installed on all Fonar scanners.

One pair is placed in each of the orthogonal imaging planes (X, Y, and Z), developing a typical readout gradient of 1.2 mT/m. Note that while the typical gradient remains at 1.2 mT/m for this submission, the value of maximum gradient change has increased from a value of 12 mT/m to a new maximum of 20.27 mT/m. The gradient linearity remains unchanged at better than 2% over a 28 cm DSV with a stability of ± 0.01%.

Gradient Current Amplifiers

The gradient current amplifier power required does not affect the actual gradient strength (which is still specified at a typical value of 1.2 mT/m with a typical amplifier power dissipation of 12 kW). The amplifiers for the Indomitable are still designed for accurate control of the current output to the gradient coils with very low distortion, and are rated for a maximum current output of 300 Amps. The gradient amplifiers are unchanged from previous submissions.

Gradient System Control

The operating characteristics for the hardware of the gradient system described above are controlled by the Indomitable's Sympulse scanner operating software. The software is programmed to operate the scanner system in a safe and efficient manner, and is substantially equivalent to the current operating software in the Indomitable system as approved in K002490. The software has always included "safety limits", which were established through laboratory testing and clinical imaging.

Prior to this submission, the maximum current value allowed by software for the gradient current amplifiers was 200 Amps. This setting effectively limited the maximum gradient amplitude (dB/dt) to 12 mT/m for the system. This rate of change produced a maximum slew rate of 19.73 mT/m/ms and allowed the Indomitable scanner to operate in the NORMAL mode. Testing performed for this submission has shown that an increase of the maximum current from the previous maximum of 200 Amps to the new maximum value of 300 Amps would still allow the scanner to be operated in the NORMAL mode, since no PNS was detected in the test subjects.

Therefore, the maximum gradient current for the gradient amplifiers will now be established by the Sympulse operating software at a value of 300 Amps. This will translate to a maximum dB/dt of 20.27 mT/m with a corresponding maximum slew rate of 33.34 mT/m/ms. The scanner will continue to operate in the NORMAL mode.

Magnet and Gradient Subsystem Comparisons

The tables of information presented below compare and summarize the common specifications for the Indomitable magnets and gradient subsystems as configured in the original submission (K002490) and in this revision. These tables show that the specifications compare favorably and therefore are substantially equivalent.

MAGNET CONFIGURATIONS	FROM 510(K) K002490	THIS SUBMISSION
Magnet Specification	Indomitable Electromagnet	Indomitable Electromagnet
Type	Iron-core Electromagnet	Iron-core Electromagnet
Field Strength	0.6 T ± 5%	0.6 T ± 5%
Operational Mode	Normal Operating Mode for both dB/dt and SAR	Normal Operating Mode for both dB/dt and SAR
Calculated SAR	0.76 W/kg	0.76 W/kg
Power Consumption	98 kVA	98 kVA
Magnet Coil Winding Material	Copper Bar with hollow core cooling	Copper Bar with hollow core cooling
Cooling	30 ton closed loop liquid chiller	30 ton closed loop liquid chiller
Stability (magnet drift)	long-term < 2 ppm/hr - short term < .3 ppm/min	long-term < 2 ppm/hr - short term < .3 ppm/min
Field Homogeneity	7 ppm within 30 cm DSV - 1 ppm within 20 cm DSV	7 ppm within 30 cm DSV - 1 ppm within 20 cm DSV
Shimming	passive only	passive only
Open Gap™ Configuration	18" transverse clearance - 8' vertical axis	18" transverse clearance - 8' vertical axis
Fringe Field (5 Gauss Line –from magnet center)	9.77 ft vertically - 13 ft to either side 9.3 ft toward front or rear	9.77 ft vertically - 13 ft to either side 9.3 ft toward front or rear
Pole Cap Eddy Current Compensation	steel pole with inlaid laminates and self-shield gradients	steel pole with inlaid laminates and self-shield gradients
Outer Dimensions (h x l x w)	128" x 142" x 87"	128" x 142" x 87"
Weight (w/ base)	290,000 lbs. (Approx.)	290,000 lbs. (Approx.)

GRADIENT SUBSYSTEM	FROM 510(K) K002490	THIS SUBMISSION
Magnet Specification	Indomitable Electromagnet	Indomitable Electromagnet
Gradient Type	three orthogonal - quadrupolar (linear) X, Y, Z	three orthogonal - quadrupolar (linear) X, Y, Z
Gradient Strength	typical readout gradient 1.2 mT/m (12 mT/m max)	typical readout gradient 1.2 mT/m (20.27 mT/m max)
Typical Rise Time	typical 0.75 msec per 15 A (1.2 mT/m equivalent)	typical 0.75 msec per 15 A (1.2 mT/m equivalent)
Maximum Slew Rate	19.73 mT/m/ms	33.34 mT/m/ms
Stability	± 0.01%	± 0.01%
Heat Dissipation	4 kW typical; 12 kW max (Air Cooled)	4 kW typical; 12 kW max (Air Cooled)

Indications for Use

The Indomitable Magnetic Resonance Imaging System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast upon NMR parameters [hydrogen nuclei concentration and flow velocity, T1 (spin-lattice relaxation time) and T2 (spin-spin relaxation time)]. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

WARNING: This device is limited by U.S. Federal law to investigational use for indications not in the indications statement.

Under the requirements of the law, the non-indicated applications can be used only under an Institutional Review Board approved protocol for a non-significant risk device or an Investigational Device Exemption application approved by the FDA for a significant risk device. The procedures to be followed, under the sponsorship of FONAR Corporation, are determined by the current guidelines established by the FDA, which should provide the IRB with sufficient guidance to determine the level of risk for a MRI device.

WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

Description of Safety and Substantial Equivalence

MRI effectiveness parameters such as spatial resolution, geometric distortion, specification volume, image uniformity, and slice spacing are unchanged by the modifications to the gradient subsystem. A series of clinical and non-clinical tests were performed to demonstrate the safety and effectiveness of the system, and to verify substantial equivalence to the predicate device. All testing was conducted in accordance with current FDA guidance documents and international standards. Results from all testing demonstrate substantial equivalence to the predicate device.

Non-Clinical Testing

The following specific parameters have been identified by the FDA as being pertinent to patient safety and thereby have been highlighted for inclusion in 510(k) submissions. The majority of these concerns are specifically tested by comparison to the ISO and NEMA standards, and where utilized are described individually.

a. Static Field Strength: 0.6T ± 5%
b. Peak and A-Weighted acoustic noise: 98.3 DBA ± 0.05
c. Description of operational modes of the system: Normal Mode Only
d. Maximum SAR for transmit coil: (Unaffected for this submission)
e. Maximum dB/dt (pulsing X, Y and Z gradients): 20.27 mT/m
f. Potential emergency conditions and shutdown: (Unaffected for this submission)
g. Biocompatibility of materials: (Unaffected for this submission)

Clinical Testing

A voluntary clinical trial was conducted under the testing guidelines described in the ISO standard IEC 60601-2-33, which describes the criteria for experimental studies of human subjects to directly determine limits related to minimizing PNS for any given type of gradient system. All volunteers participated in the study under informed consent. All volunteers completed the test. During the testing process, no volunteer experienced any sensations associated with PNS. This result meets the criteria for continued operation in the normal mode for the Indomitable scanner with the new maximum current limits.

Summary

The results of the testing, combined with the additional material presented within this submission has demonstrated that the modified gradient subsystem of the Indomitable magnet is substantially equivalent to the previously approved gradient subsystem of the predicate device (K002490) under the current conditions for intended use, with no adverse effects to patient health or safety reported.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 2 8 2006

Mr. Luciano Bonanni
Executive Vice President
Fonar Corporation
110 Marcus Drive
MELVILLE NY 11747-4292

Re: K061930
Trade/Device Name: Indomitable Magnetic Resonance Imaging Scanner
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 5, 2006
Received: July 7, 2006

Dear Mr. Bonanni:

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

STATEMENT OF INDICATIONS FOR USE

Applicant: FONAR CORPORATION
510(k) Number (if known): K061930
Device Name: Indomitable Magnetic Resonance Imaging Scanner

Indications For Use:

The Indomitable Magnetic Resonance Imaging System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast upon NMR parameters [hydrogen nuclei concentration and flow velocity, T1 (spin-lattice relaxation time) and T2 (spin-spin relaxation time)]. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061930