K063207

NOV - 9 2006

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1) **Submitter Information**

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Date: October 19, 2006

807.92(a)(2)

Trade Name: S-scan

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic resonance diagnostic device

Classification Number: 90LNH

807.92(a)(3) **Predicate Device(s)**

Esaote	G-scan	K042236
Esaote	E-scan Opera	K060956
Siemens	Magnetom C!	K043030
USA Instruments	Magna 5000 Phased Array CTL Spine Coil	K994345

807.92(a)(4) **Device Description**

Summary of G-scan modifications

The changes performed on the modified G-scan device (S-scan), with respect to the cleared version – G-scan K042236 –, are due to the improvement of the system performance. These modifications, that do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

1. A new patient table that can be moved only manually. Neither the patient table nor the magnet can rotate from horizontal to vertical position.
2. A modified support to hold up the magnet and the gantry.
3. A new display panel on the front of the magnet.
4. Some different external covers due to the new patient table and support.
5. Upgrading of the electronics.
6. Two new receiving coils: DPA Lumbar spine coil N.10 and Cervical spine coil N.9
7. Modified pulse sequences
8. A modified version of the magnet poles and of the gradient coils.
9. A new software release.

S-scan

The system is composed of these main parts:
1. Patient positioning table.
2. Magnetic unit with the display panel.
3. Operating console that consists of the PC unit (including keyboard and mouse), the monitor and the operating table.
4. Electronics box with filter panel.

807.92(a)(5) **Intended Use(s)**

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging portions of the spinal column, including the cervical and lumbo-sacral sections.

S-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

807.92(a)(6) **Technological Characteristics**

Characteristic	S-scan	G-scan K042236	Comments
Pulse Sequences	Orthogonal Multi-planar Scout Spin Echo T1 Spin Echo T2 Spin Echo Proton Density T2 Inversion Recovery Short TI Inversion Recovery Spin Echo T1 Half Echo Spin Echo T1 Half Fourier Turbo Spin Echo T2 weighted (TSE, TSE S, TSE SA, TSE SP) Turbo Multi Echo Gradient Echo Short Time Inversion Recovery Gradient Echo (Gradient Echo STIR) Gradient Echo 3D (Turbo 3D T1) Speed – Spin Echo T2 (SSE-SET2, SSE-SET2 S, SSE-SET2 SA, SSE-SET2 SP) Speed – Spin Echo T2 (SSE-SET2 # 1-2-3) Real Time	Orthogonal Multi-planar Scout Spin Echo T1 Spin Echo T2 Spin Echo Proton Density T2 Inversion Recovery Short TI Inversion Recovery Spin Echo T1 Half Echo Spin Echo T1 Half Fourier Turbo Spin Echo T2 weighted (TSE) Turbo Multi Echo Gradient Echo Short Time Inversion Recovery Gradient Echo (Gradient Echo STIR) Gradient Echo 3D (Turbo 3D T1) Real Time	The S-scan pulse sequences are a modified version of the G-scan pulse sequences as described in the Device Modification Description and Software Description sections.
Receiving coils	1 Shoulder coil 2 Knee coil 3 Hand coil 4 Foot/Ankle coil 6 Flexible coil 7 Shoulder coil 9 Cervical Spine coil 10 Lumbar Spine coil	1 Shoulder coil 2 Knee coil 3 Hand coil 4 Foot/Ankle coil 6 Flexible coil 7 Shoulder coil 8 Thoracic – Lumbar Spine coil 9 Cervical Spine coil	The linear coil of the DPA Lumbar Spine coil n.10 is equal to the Thoracic – Lumbar Spine coil n.8. The whole coil is equivalent to the Magna 5000 Phased Array CTL Spine Coil K994345, available on other commercial scanners. See Device Modification Description section.

Characteristic	S-scan	G-scan K042236	Comments
Multi-channel reconstruction	SoS technique		This technique is already in place on many multi-channel MRI systems as, for instance, MAGNETOM C! (K043030). See Device Modification Description section.
Indications for Use	S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging portions of the spinal column, including the cervical and lumbo-sacral sections. S-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.	G-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging portions of the spinal column, including the cervical, thoracic and lumbo-sacral sections. G-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained he use of MR equipment, the images can provide diagnostically useful information.	

Characteristic	S-scan	E-scan Opera K060956	Comments
Patient table	Maximum load-bearing capacity = 200 kg (approx. 440 lb) fixed height (740 cm) it can be rotated and removed from magnet cavity to facilitate patient positioning and to enable various positions in relation to the region examined washable covering material manual positioning integrated in overall design of equipment.	Maximum load-bearing capacity = 200 kg (approx. 440 lb) fixed height (710 cm) removable from magnet cavity to facilitate patient positioning one section of the bed can be rotated to enable various positions in relation to the region examined washable covering material manual positioning integrated in overall design of equipment.	See Device Modification Description section
Magnetic unit display panel	The function of the Display Panel is displaying real time sequences for patient positioning. Present commands: Preview: begins the real time sequence and displays the acquired image on the LCD panel in the selected orientation (sagittal, axial, coronal). Abort: stops the running sequence.	The function of the Display Panel is displaying real time sequences for patient positioning. Present commands: Preview: begins the real time sequence and displays the acquired image on the LCD panel in the selected orientation (sagittal, axial, coronal). Abort: stops the running sequence.	See Device Modification Description section
Electronics box	ALDIM unit: supplies the Display Panel.	ALDIM unit: supplies the Display Panel.	See Device Modification Description section.
Image visualization	RF saturation pulses to suppress flow and motion artifacts. The Repetition Time (TR) of each sequence can be set using fixed step so that 50 or 60 Hz artifacts can be avoided. Algorithm to avoid wrap around artifacts through oversampling. Flow compensation through the Gradient moment nulling technique.	RF saturation pulses to suppress flow and motion artifacts. The Repetition Time (TR) of each sequence can be set using fixed step so that 50 or 60 Hz artifacts can be avoided.	The oversampling and the gradient moment nulling (GMR – Gradient Motion Rephasing) are available on other commercial scanners as, for instance, MAGNETOM C! (K043030). See Software Description section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Esaote, S.p.A.
% Ms. Carri Graham
Official Correspondent
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CARMEL IN 46032

NOV - 9 2006

Re: K063207
Trade/Device Name: S-scan MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 19, 2006
Received: October 23, 2006

Dear Ms. Graham:

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

Indications for Use

510(k) Number (if known): K063207

Device Name: S-scan MRI System

Indications for Use:

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging portions of the spinal column, including the cervical and lumbo-sacral sections.

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Prescription Use __X____ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063207