K080968

APR 2 9 2008

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: April 3, 2008

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	S-scan	K063207
Esaote	G-scan	K042236
Siemens	Magnetom C!	K043030
Esaote	Dynamic MRI Software for C-scan, E-scan XQ, & E-scan Opera	K061429
Siemens	Syngo Multimodality Workstation	K010938

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

Summary of S-scan modifications

The changes performed on the modified S-scan device, with respect to the cleared version – S-scan K063207 –, 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 device that locks the patient table in the current position, unless the user disconnects the coil cable.
2. A limb protection for patient table.
3. Modified pulse sequences.
4. A new software release.

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 modified	S-scan K063207	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) FSE (FSE T1, FSE STIR, FSE T2) 3D HYCE XBONE 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, 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	The modified S-scan pulse sequences are described in the Device Modification Description.
Sequence parameters	Spin Echo T1, TE=16 ms: TR: from 50 to 5000 ms, step 10 ms TE: 16 ms FA: 90° FOV: from 100 to 300 mm, step 10 mm Slice thickness: from 2 to 10 mm, step 0.5 mm	See comments	This is a particular version of standard Spin echo T1 with TE fixed at 16 ms, instead of 18 ms.
Sequence parameters	Speed - Spin Echo T2 #1: TR: from 200 to 5000 ms, step 10 ms TE: 130 ms FA: 90° FOV: from 250 to 400 mm, step 10 mm Slice thickness: from 4 to 10 mm, step 0.5 mm Speed - Spin Echo T2 #2: TR: from 200 to 5000 ms, step	See comments	The Speed Spin Echo T2 #1, 2, 3 are the Spin Echo T2 #1, 2, 3 sequence with Speed technique for reduction of scan time.

Characteristic	S-scan modified	S-scan K063207	Comments
	10 ms TE: 130 ms FA: 90° FOV: from 250 to 400 mm, step 10 mm Slice thickness: from 4 to 10 mm, step 0.5 mm <u>Speed - Spin Echo T2 #3:</u> TR: from 200 to 5000 ms, step 10 ms TE: 130 ms FA: 90°. FOV from 250 to 400 mm, step 10 mm Slice thickness: from 4 to 10 mm, step 0.5 mm		
Sequence parameters	<u>FSE T2</u> ESP: 20 ms, 30 ms ETL: from 8 to 12 (depending of ESP selected), step 2 TR: from 100 to 10000 ms, step 10 ms TE: from 20 to 300 ms, step 20 ms or 30 ms (depending of ESP and ETL selected) FA: 90° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 3 to 7 mm, step 0.5 mm Flow compensation: None/Read /Sel Relaxation: Yes/No <u>FSE STIR:</u> ESP: 20 ms, 30 ms ETL: from 2 to 6 (depending of ESP selected), step 2 TR: from 100 to 10000 ms, step 10 ms TE: from 20 to 120 ms, step 20 ms or 30 ms (depending of ESP and ETL selected) TI: from 60 to 300 ms, step 5 ms FA: 90° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 3 to 7 mm, step 0.5 mm Flow compensation: None/Read /Sel	See comments	See Device Modification Description - Modified pulse sequences section.

Characteristic	S-scan modified	S-scan K063207	Comments
	FSE T1 ESP: 20 ms ETL: 2, 3 TR: from 100 to 10000 ms, step 10 ms TE: from 20 to 60 ms, step 20 ms (depending of ETL selected) FA: 90° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 3 to 7 mm, step 0.5 mm		
Sequence parameters	GE T2 FC: TR: from 30 to 5000 ms, step 5 ms TE: from 22 to 34 ms, step 4 ms FA: from 10° to 90°, step 5° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 2 to 10 mm, step 0.5 mm	See comments	This is a particular version of the Gradient echo T2 standard sequence with application of gradient moment nulling technique for flow compensation. See Software Description - Software Requirements Specifications section.
Sequence parameters	Gradient Echo, TE=6 ms: TR: from 30 to 5000 ms, step 5 ms TE: 6 ms FA: from 10° to 90°, step 5°. FOV: from 130 to 300 mm, step 10 mm Slice thickness: from 4 to 10 mm, step 0.5 mm	See comments	This is a Gradient echo sequence with fixed TE at 6 ms that provides "pseudo T1"contrast images.
Sequence parameters	STIR T2 S: TR: from 200 to 10000 ms, step 10 ms TE: from 120 to 130 ms, step 10 ms TI: from 50 to 2000 ms, step 5 ms FA: 90° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 3 to 10 mm, step 0.5 mm	See comments	This is a STIR standard sequence with 4 echoes instead of 3 that are combined to obtain T2-weighted contrast images with better S/N.
Sequence parameters	STIR T2 A: TR: from 200 to 10000 ms, step 10 ms TE: from 80 to 120 ms, step 10	See comments	This is a particular version STIR standard sequence where the sequence parameters

Characteristic	S-scan modified	S-scan K063207	Comments
	ms TI: from 50 to 2000 ms, step 5 ms FA: 90° FOV: from 120 to 400 mm, step 10 mm Slice thickness: from 3 to 10 mm, step 0.5 mm		are optimized for joint visualization.
Sequence parameters	XBONE TR: from 50 to 5000 ms, step 10 ms FA: from 10° to 90°, step of 5° FOV: from 100 to 400 mm, step 10 mm Slice thickness: from 2 to 10 mm, step 0.5 mm	See comments	See Device Modification Description – section Modified pulse sequences.
Sequence parameters	3D HYCE TR: from 10 to 13 ms TE: TR/2 FA: from 60° to 90° FOV: from 200 to 300 mm, step 10 mm FOV 3D: from 80 to 160 mm, step 10 mm Slice thickness: from 0.8 to 20 mm, step 0,1 mm	See coments	See Device Modification Description – Modified pulse sequences section.

Characteristic	S-scan modified	G-scan K042236	Comments
Pulse sequences	FSE (FSE T1, FSE STIR, FSE T2)	Turbo Spin Echo – 7	See Device Modification Description – Modified pulse sequences section.

Characteristic	S-scan modified	MAGNETOM C! K043030	Comments
Pulse sequences	FSE T2 with relaxation technique	RESTORE sequence	See Device Modification Description – Modified pulse sequences section.

Characteristic	S-scan modified	MAGNETOM C! K043030	Comments
Pulse sequences	3D HYCE	trueFISP	See Device Modification Description – Modified pulse sequences section.

Characteristic	S-scan modified	MAGNETOM C! K043030	Comments
Pulse sequences	XBONE	Dixon Fat Suppression	See Device Modification Description – Modified pulse sequences section.

Characteristic	S-scan modified	Dynamic MRI Software K061429	Comments
Image Processing Functions	Dynamic MRI study environment: - Display by group - Automatic registration of the group's images - Generate, save and export of uptake curves and of comparison between two different uptake curves - Management of dynamic acquisition by pedal switch (identification of the dynamic acquisition starting time)	Dynamic MRI study environment: - Display by group - Generate, save and export of uptake curves.	The registration technique is already in place on many diagnostic imaging devices or post-processing workstations as, for instance, *syngo* Multimodality Workstation - feature Image Fusion(K010938). See Software Description - Software Requirements Specifications section.

Characteristic	S-scan modified	S-scan K063207	Comments
Networking functions	- Possibility of reading, writing and update of CD-R and DVD in DICOM format, (FSC, FSR, FSU General Purpose CD-R Image Interchange Profile, MR images only). - Possibility of exporting images both in DICOM and in jpeg format on the same removable media (at least the DICOM format is always present).	Possibility of reading, writing and update of CD-R in DICOM format, (FSC, FSR, FSU General Purpose CD-R Image Interchange Profile, MR images only).	See Software Description - Software Requirements Specifications section.
Access to the system	- Management, only by system administrator, of two levels of security. - Possibility, only by system administrator, to reset the password of the users.	Management of multiple users with automatic expiry of password and account (if not used).	See Software Description - Software Requirements Specifications section.
Accessories	Viewer Lite :	Viewer Lite :	See Software Description -

Characteristic	S-scan modified	S-scan K063207	Comments
	- export on a CD/DVD and display on a commercial PC of the Esaote's MRI images - copy of the Viewer Lite user manual on the CD/DVD	- export on a CD/DVD and display on a commercial PC of the Esaote's MRI images.	Software Requirements Specifications section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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APR 29 2008

Re: K080968
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: April 3, 2008
Received: April 4, 2008

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): _____

Device Name: S-scan MRI System

Indications for Use:

S-scan is a Magnetic Resonance (MR) system that produces transverse, 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.

The indications for use of the S-scan system, as described in its labeling, are the same as those of the unmodified S-scan system cleared via K063207.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083968