K042236

OCT 4 - 2004

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

Carri Graham, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Carri Graham

Date: August 13, 2004

807.92(a)(2)

Trade Name: G-scan

Common Name: Magnetic resonance diagnostic device

Classification Name(s): System, Nuclear Magnetic Resonance Imaging

Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

Tradename	Common name	Class	Product code	Manufacturer	K number
E-scan XQ	System, nuclear magnetic resonance imaging	II	**LNH**	ESAOTE S.P.A.	K032121
AIRIS II	System, nuclear magnetic resonance imaging	II	LNH	HITACHI MEDICAL SYSTEMS	K001334
MAGNA SL	System, nuclear magnetic resonance imaging	II	LNH	MAGNA-LAB	K940894
Magna 5000 Phased Array CTL Spine Coil	Coil, Magnetic Resonance, Specialty	II	MOS	USA INSTRUMENTS	K994345
UROLOGIC	Table, radiographic, tilting	II	IXR	PCK ELECTRONIC INDUSTRY	K011311

?01.92(a)(4)

Device Description

G-scan is an open MRI system designed specifically to image limbs, joints and the spinal column.

The system is equipped with a hydraulic mechanism that will rotate both the magnet and the patient table from horizontal to vertical position, as shown in the following figures.

The patient may be scanned while lying down in a horizontal position and later he can be scanned vertically, in the weight bearing state, limited to the ankle, knee, hip and shoulder joint, and the spine.

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

807.92(a)(5)

Intended Use(s)

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 in the use of MR equipment, the images can provide diagnostically useful information.

807.92(a)(6)

Technological Characteristics

1. Imaging System

Characteristic	G-scan	AIRIS II K001334	Comments
Clinical use	Portions of the upper limb, including hand, wrist, forearm, elbow, arm and shoulder. Portions of the lower limb, including foot, ankle, calf, knee, thigh and hip. Portions of the spinal column, including the cervical, thoracic and lumbo-sacral sections.	Whole body, central nervous system and orthopaedic regions.	The spinal column has been introduced for examination.
Pulse sequences	Turbo Spin Echo 7	Fast Spin Echo	All the other pulse sequences are the same of E-scan XQ, K032121. The Turbo Spin Echo 7 is described in the "Device Description" section.
Field of view	From 100 up to 350 mm, step 10 mm (250 mm are displayed).	From 50 up to 350 mm, step 1 mm	A larger FOV is available to better cover the anatomical parts to be imaged.

2. Magnetic System

Characteristic	G-scan	AIRIS II K001334	Comments
Static field intensity	0.24 T.	0.3 T	
Fringe field	0.5 mT line at 1.8 m maximum from the centre of the magnet.	0.5 mT line at 2.5 m maximum from the centre of the magnet.	
Gantry opening	33 cm high	38 cm high	

Characteristic	G-scan	MAGNA SL K940894	Comments
Field direction	Vertical or horizontal, according to system orientation, between the two "C" faces	Vertical or horizontal, according to system orientation, between the two "C" faces	The rotation of the magnet , together with the patient table, allows the weight bearing examination. The rotation system is described in the "Device Description" section.

Characteristic	G-scan	E-scan XQ K032121	Comments
Homogeneity	< ± 4 ppm (FWHM) on 250 mm DSV	< ± 4 ppm (FWHM) on 140 mm DSV	A larger homogeneity region has been realized to cover the anatomical parts to be imaged.

3. Gradients System

Characteristic	G-scan	E-scan XQ K032121	Comments
Maximum Intensity	± 20 mT/m	± 20 mT/m	Unchanged
Rise time	0.8 ms (from 0 to 99%)	0.8 ms (from 0 to 99%)	Unchanged
Linearity	± 5 % on 250 mm DSV	± 5 % on 140 mm DSV	The linearity covers the homogeneity region.

4. Radiofrequency System

Characteristic	G-scan	AIRIS II K001334	Comments
RF power	up to 1800 W peak pulse	up to 5000 W peak pulse	

Characteristic	G-scan	E-scan XQ K032121	Comments
Receiving chain	noise figure < 1 dB	noise figure < 1 dB	The receiving

Characteristic	G-scan	E-scan XQ K032121	Comments
	bandwidth at 0.5 dB: 600 kHz (10.2 MHz ± 300 kHz) maximum coil/preamplifier system output –3 dBm Chain gain programmable in a 75 dB range with two gain states with 256 levels each	bandwidth at 0.5 dB: 600 kHz (7.7 MHz ± 300 kHz) maximum coil/preamplifier system output –3 dBm Chain gain programmable in a 75 dB range with two gain states with 256 levels each	chain bandwidth is centered around the center frequency of the G-scan magnet.
Transmission Coil	2 linear flat coils: one on the upper side and the other on the lower side of the gantry IN-impedance = 50 ohm active detuning during receiving through PIN diodes – 5 V 100 mA	linear saddle coil IN-impedance = 50 ohm active detuning during receiving through PIN diodes –5 V 100 mA	The upper and lower transmission coil of E-scan XQ are connected to obtain a single linear coil that is excited by a single 900 W RF amplifier. The upper and lower transmission coil of G-scan are not connected and each one is excited by a single 900 W RF amplifier.
Transmission chain	2 RF power amplifier until 900 W pep bandwidth 9.5÷11.5 MHz gain stability 0.1 dB	1 RF power amplifier until 900 W pep bandwidth 7÷9 MHz gain stability 0.1 dB	The RF amplifiers of G-scan are the same of E-scan XQ, with the bandwidth centered around the center frequency of the G-scan magnet.

Characteristic	G-scan	Magna 5000 Phased Array CTL Spine Coil K994345	Comments
Linear receiving coil	Thoracic – Lumbar Spine coil	THORACIC CTL NB (Thoracic) and LUMBAR CTL NB (Lumbar) Coil Selections for GE OpenSpeed 0.7T Systems	The G-scan coil is a linear coil equivalent to the linear part of the Magna 5000 coil, i.e. the Magna 5000 coil without the bridges that make it a quadrature coil. The Thoracic – Lumbar Spine coil is described in the "Device Description" section.

5. Patient Positioning

Characteristic	G-scan	AIRIS II K001334	Comments
Patient table	Automatic movement in longitudinal direction (referred to the patient), stroke 140 cm Manual movement in lateral direction (referred to the patient), of tabletop only, ± 25 cm Fixed height	Longitudinal automatic movement, stroke 175 cm Lateral automatic movement ± 5 cm Vertical automatic movement 45 ÷ 70 cm	The automatic movement system of G-scan is described in the "Device Description" section

Characteristic	G-scan	UROLOGIC K011311	Comments
Patient table	Automatic rotation, including the magnetic system, from 0° to 90°.	Motorized tilting movement, including the x-ray tube, from -16° to 90°.	The automatic movement system of G-scan is described in the "Device Description" section

6. Installation Area Conditions

Characteristic	G-scan	AIRIS II K001334	Comments
Area necessary	4.1 m x 3.85m (magnetic unit) 4.1m x 1.65 m (operator console and electronics box)	4 m x 5 m (gantry and patient table) 4 m x 2.5 m (operator console, MRI unit and other components)	
Floor load	Floor that can take a total weight of about 8500 Kg (including patient and operator).	Floor that can take a total weight of about 11300 Kg (including patient and operator).	

7. Power Supply

Characteristic	G-scan	AIRIS II K001334	Comments
Power supply	Single phase 200/208/220/230/240 VAC, 50/60 Hz, 24 hours	Single phase 200/208/220/230/240 VAC, 8 kVA	
Power consumption	1200 VA during rapid heating; 3000 VA during normal operation; 450 VA with unit OFF (thermal control)	Approx. 3 kW	

Characteristic	G-scan	E-scan XQ K032121	Comments
Over-current release	Thermal Circuit Breaker: primary circuit: 200÷240 V: 25 A secondary circuit: 20 A	Main Fuses: primary circuit: 200÷240 V: 6.3 A 100÷110 V: 15 A secondary circuit: 6.3 A	G-scan needs a protective device, capable of carrying and breaking greater currents
Earthing	via power supply cable of 1.5 mm2 section	via power supply cable of 1.5 mm2 section	Unchanged

8. Shielding box

Characteristic	G-scan	E-scan XQ K032121	Comments
Attenuation	*attenuation:* *RF 8-12 MHz E field 70 dB* *AC 16.6 Hz H field 1.7* *AC 50/60 Hz H field 3.0*	*attenuation:* *RF 7-9 MHz E field 70 dB* *AC 16.6 Hz H field 1.7* *AC 50/60 Hz H field 3.0*	Unchanged
Weight	600 kg	600 kg	Unchanged
Dimensions	3.95 x 3.65 x 2.35 (w x d x h)	3.85 x 3.85 x 2.65 (w x d x h)	The G-scan shielding box is described in the "Device Description" section

Note: Any deviations from original E-scan XQ specifications are substantiated within Quality System documentation at Esaote S.p.A..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Esaote, S.p.A.
% Ms. Carrie Graham
Consultant
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K042236
Trade/Device Name: G-Scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: August 13, 2004
Received: August 18, 2004

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.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" (21 CFR 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 (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

Indications for Use

510(k) Number (if known):

Device Name: G-scan

Indications For Use:

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 in the use of MR equipment, the images can provide diagnostically useful information.

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)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042236