K032121

AUG 1 3 2003

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: June 30, 2003

807.92(a)(2)

Trade Name: E-Scan XQ

Common Name: Magnetic resonance diagnostic device

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

Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

Esaote	Artoscan M	K963262
Esaote	E-Scan	K990968
Esaote	E-Scan	K001894
Esaote	Hip Coil	K012728
Esaote	E – Scan XQ	K020164

807.92(a)(4)

Device Description

Summary of E-scan XQ modifications
The changes performed on the E-scan XQ device, with respect to the cleared version – E-scan XQ K020164 -. 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. Modified system configuration.
2. New operating tables.
3. Upgrading of the electronics.
4. A new software release.

System configuration

Unmodified E-scan XQ
The unit is composed of these main parts:

1. Patient positioning table.
2. Magnetic unit.
3. Console, made of the Operating console (mouse, keyboard, monitor, ODD, FDD and CD-RW) and the Electronics box.
4. Modular shielding box with filter panel.

Modified E-scan XQ
The system is composed of these main parts:

1. Patient positioning table.
2. Magnetic unit.
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.
5. Modular shielding box.

807.92(a)(5)

Intended Use(s)

E-scan XQ is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross–section images of the limbs and joints. It is intended for imaging the arm, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging the leg, including the foot, ankle, calf, knee, thigh and hip.

E-scan XQ MR 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.

Technological Characteristics

Comparison to the cleared device
E-scan XQ K020164

Imaging system

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Pulse sequences	Orthogonal Multi-planar Scout Spin Echo T1 (set1) Spin Echo T2 (set2) Multi-Echo (se_pd_t2) Inversion Recovery (ir) Short TI Inversion Recovery (stir) Spin Echo Half Echo (set1he) Spin Echo Half Scan (set1hf) Turbo SE T2 weighted and Turbo ME (tse, tme) Gradient Echo (ge) Short Time Inversion Recovery Gradient Echo (ge_stir) Gradient Echo 3D (t3d_t1) Gradient Echo 3D contrast enhancement (3d_ce) Real Time	Orthogonal Multi-planar Scout Spin Echo T1 (set1) Spin Echo T2 (set2) Multi-Echo (se_pd_t2) Inversion Recovery (ir) Short TI Inversion Recovery (stir) Spin Echo Half Echo (set1he) Spin Echo Half Scan (set1hf) Turbo SE T2 weighted and Turbo ME (tse, tme) Gradient Echo (ge) Short Time Inversion Recovery Gradient Echo (ge_stir) Gradient Echo 3D (t3d_t1) Gradient Echo 3D contrast enhancement (3d_ce) Real Time	Unchanged
Sequence parameters		<u>High Resolution se_26:</u> TR from 60 ms to 5000 ms, step 1 ms TE fixed at 26 ms minimum FOV 100 mm minimum slice thickness 2.0 mm <u>High Resolution se_26_hf:</u> TR from 60 ms to 5000 ms, step 10 ms TE fixed at 26 ms minimum FOV 100 mm minimum slice thickness 2.0 mm	The high resolution sequences are a particular version of the E-scan XQ standard sequences with maximum acquisition matrix 512x512 instead of 256x256. All these sequences have a fixed TE for obtaining the best compromise between the S/N and the high resolution. High Resolution se_26: it is a Spin Echo T1 sequence with TE=26 msec.

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
		High Resolution se_18_he TR from 60 ms to 5000 ms, step 10 ms TE fixed at 18 ms minimum FOV 120 mm minimum slice thickness 2.0 mm High Resolution tse_80: TR from 200 ms to 5000 ms, step 10 ms TE fixed at 80 ms minimum FOV 120 mm minimum slice thickness 3.0 mm High Resolution tse_50: TR from 200 ms to 5000 ms, step 10 ms TE fixed at 50 ms minimum FOV 120 mm minimum slice thickness 3.0 mm High Resolution tme: TR from 200 ms to 5000 ms, step 10 ms TE: first echo 28 ms, second echo 90 ms minimum FOV 120 mm minimum slice thickness 3.0 mm High Resolution ge_16: TR from 35 ms to 5000 ms, step 5 ms TE fixed at 16 ms FA from 10° to 90°, step 5° minimum FOV 130 mm minimum slice thickness 2 mm High Resolution ge_stir_25: TR from 150 ms to 5000 ms, step 10 ms TE fixed at 25 ms minimum FOV 130 mm minimum slice thickness 3 mm	High Resolution se_26_hf: it is a Spin Echo T1 Half Fourier sequence with TE=26 msec. High Resolution se_18_he: it is a Spin Echo T1 Half Echo sequence with TE=18 msec. High Resolution tse_80: it is a Turbo Spin Echo T2 sequence with TE=80 msec. High Resolution tse_50: it is the high resolution version of the standard sequence Turbo Spin Echo T2, TE=50 ms. High Resolution tme: it is the high resolution version of the standard sequence Turbo Multi-echo. High Resolution ge_16: it is a Gradient Echo sequence with TE=16 msec. High Resolution ge_stir_25: it is the high resolution version of the standard sequence Gradient Echo STIR, TE=25 ms.

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Acquisition Matrix:	2D FT: from 192x 128 to 256x256; phase encoding step 8 3D FT: from 192x128 to 256x256; slice encoding from 24 to 128, step 8; phase encoding step 8	2D FT for non High Resolution: from 192x 128 to 256x256; phase encoding step 8 2D FT for High Resolution: from 192x 128 to 512x512; frequency encoding step 32, phase encoding step 8 3D FT: from 192x128 to 256x256; slice encoding from 24 to 128, step 8; phase encoding step 8	To perform High resolution sequences is necessary that the raw data matrix dimensions are increased, i.e. it's necessary to increase the number of readout (frequency) sampling points and the number of phase encoding steps.

Magnetic System

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Fringe Field (0,5 mT line):	X direction (horizontal) : 1,5 m front; 1,2 rear Y direction (vertical) : 1,3 m Z direction (horizontal right/left): 1,5 m	X direction (horizontal) : 1,34 m front; 1,06 rear Y direction (vertical) : 1,25 m Z direction (horizontal right/left): 1,29 m	More precise characterization of the data

Gradients System

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Control System:	Digital, based on DSP SHARC 66 Mips, 132 MFlops, 0.5 Mbit Memory on the chip 1.1515 nsec Instruction rate 4 independent channels (X - Y - Z - Bo) DAC 18 bit - updating every 7.2 µs Ramp generation - preemphasis of eddy current compensation - adjustable delay	Digital electronic, based on DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM 4 independent channels (X,Y,Z, B_0) DAC 18 bit – update every 7,2 µs Ramp generation – pre-emphasis of eddy current suppression – adjustable delay	Technological updating
Magnetic compensation system:	*"open loop" control of the magnetic field variation with external measurement (AC and DC probes); digital elaboration of the signal in separated channels (DC - 50/60 Hz - 16.6. Hz) and correction with Bo coil.* *Digital electronic based on DSP SHARC 66 Mips,132 MFlops, 0.5 Mbit Memory on the chip*	*"open loop" control of the magnetic field variation with external measurement (AC and DC probes); digital elaboration of the signal in separated channels (DC - 50/60 Hz - 16.6. Hz) and correction with Bo coil.* *Digital electronic, based on DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM*	Technological updating

Radiofrequency System

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
A/D Conversion:	baseband conversion and demodulation of the RF received signal in phase and quadrature components 2 A/D converter 16 bit 78 kHz sampling 2 digital low-pass filter for analogical phase and quadrature components; bandwidth: gain 1 up to 0.464xfc, con fc = 78.125 KHz/n, n=1÷10; stop-band: from 0.5xfc; attenuation 90 dB	For each channel: 3 MHz conversion of the RF received signal A/D converter 14 bit 20.MHz sampling digital demodulation in phase and quadrature components digital low-pass filter; bandwidth: gain 1 up to 0.43 x fc, with fc from 156.25 to 4.882 kHz; stop-band: from 0.5 x fc; attenuation 90 dB	Technological updating. A more detailed decription is in the the section "Device modification description".
Synthesizer:	digital, through DSP SHARC 66 Mips, 132 MFlops, 0.5 Mbit Memory on the chip, with frequency, amplitude and phase modulation resolutions: 1,2 Hz frequency, 256 levels amplitude, 1' 4° phase stability : < 1 ppm into the operative temperature range transmission variable gain: 256 levels	digital, through DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM, with frequency, amplitude and phase modulation resolutions: 28.4 µHz frequency, 4096 levels amplitude, 5' 16 " phase stability : < 1 ppm into the operative temperature range transmission variable gain: 256 levels	Technological updating
Transmission Coil:	linear saddle shape coil IN-impedance = 50 ohm passive detuning during receiving through BYW29 diodes	linear saddle shape coil IN-impedance = 50 ohm active detuning during receiving through PIN diodes –5 V 100 mA	The diodes, detuning the transmitting coil to the NMR frequency during the reception, avoid that the transmitting coil could receive partially the NMR signal. On the other hand the lateral lobes of the transmitting pulse are distorted by the BYW29 diodes. This effect is avoided with the introduction of the PIN diodes.
Transmission chain:	RF power amplifier until 600 W pep bandwidth 7÷9 MHz gain stability 0.1 dB	RF power amplifier until 900 W pep bandwidth 7÷9 MHz gain stability 0.1 dB	The modifications of the RF amplifier are described in the section "Device modification description".

Image Processing and Display System

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Central Processing Unit	ISA and PCI Bus CPU Pentium III 850 MHz or faster main memory: 256 MB secondary cache memory: 256 KB or upper	PCI bus CPU Pentium IV 2.4 GHz or more Main memory: 1 GB Secondary cache memory: 512 KB or more	Technological updating
Control processor	36 MIPS, 72 MFlops, 0.25 MB memory	DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM + 384 KB SSRAM	Technological updating
Acquisition and reconstruction processor:	36 MIPS, 72 MFlops, 0.5 MB memory + 128 MB DRAM	DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM + from 256 to 512 MB SDRAM + 1.28 MB SSRAM	Technological updating
Hard Disk Unit	3"$^{1}/_{2}$ hard disk; at least 20 GB, 7200 rpm	3"$^{1/2}$ hard disk; at least 40 GB, 7200 rpm	Technological updating
Image Reconstruction Matrix:	2D: 256x256 3D: 256x256x8 to 256x256x128 step 8	2D: 128x128, 256x256, 512x512 3D: 256x256x24 to 256x256x128 step 8	The visualization matrix of the images obtained by the high resolution sequences can be 128x128, 256x256 or 512x512 pixels.
Display monitor	19" CRT Colour 17" TFT Colour 1280 x 1024 pixel at least 70 Hz. not-interleaved high contrast	*18.1" TFT Color* *1280x 1024 pixel* *not interleaved 60 Hz* *high contrast*	Technological updating

Patient positioning

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Cushion of the rotating portion of the Patient Table	Composition of the material covering the cushion: Wild Heather Ambla (DBL) foamed PVC on a fire retardant cotton support	Composition of the material covering the cushion: Coverlim 27 New (LIMONTA) 56% Cotton 44% Polyurethane	The evaluation of the new material is described in the section "Biocomaaptibility Sumary".

Installation Area Conditions

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Vibrations:	< -70 dBg da 0 a 100 Hz	< -65 dBg from 0 to 100 Hz warning range with standard feets: 9÷13 Hz warning range with vibration-damping springs: 4÷7 Hz	The vibration-damping springs can be used, instead of the standard feets, to install the system in sites with important vibrations in the frequency range 9 ÷13 Hz for lowering the resonance frequency of the magnet from 11 Hz to 5.9 Hz. The final effect is the image quality enhancement from the artifacts point of view, as the mechanical vibrations cause a variation of the magnetic field intensity and consequently ghost artifacts on the images.

Power supply

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Power consumption:	1100 VA during quick magnet heating 800 VA during normal working 200 VA when unit is powered off (thermal control on)	1000 VA during quick magnet heating 800 VA during normal working 200 VA when unit is powered off (thermal control on)	More precise characterization of the data.

Dimensions and weights

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Composition of the device	Magnetic Unit with Patient Positioning table Console	Magnetic Unit with Patient Positioning table Electronic box Operating Table with Personal Computer	The new composition is described in the section "Device Modification Description".
Console:	Width 0.844 m; Depth 0.940 m; Height 0.735 m; Weight 150 Kg	Not available	
Electronics box:	Not available	Width 0.793 m; Depth 0.632 m; Height 1.563 m; Weight 150 Kg	The electronics box is described in the section "Device modification description".
Personal Computer:	Not available	Width 26 cm; Depth 44 cm; Height 43 cm; Weight 15 Kg	The PC is described in the section "Device modification description".

Accessories

Characteristics	E-scan XQ K020164	E-scan XQ modified	Comments
Operating table:	*Not available*	*Available in two models* *High version: width 108 cm; depth 88 cm; height 74 cm;* *weight: 78 kg* *Comfort version: width 108 cm; depth 80 cm; height 74 cm;* *weight: 59 kg*	*The operating tables are described in the section "Device modification description".*
Shielding box	*Shielding box made of Fe* *attenuation:* *RF 70 dB* *DC magnetic field 1.0* *AC 16.6 Hz magnetic field 1.5* *AC 50/60 Hz magn. field 2.6* *weight: 1300 Kg* *Shielding box made of Al* *attenuation:* *RF 70 dB* *DC magnetic field 1.0* *AC 16.6 Hz magnetic field 1.8* *AC 50/60 Hz magn. field 4.0* *weight: 500 Kg*	*Shielding box made of Al* *attenuation:* *RF 70 dB* *DC magnetic field 1.0* *AC 16.6 Hz magnetic field 1.8* *AC 50/60 Hz magn. field 4.0* *weight: 500 Kg*	*The Shielding Box made of Fe is not available any more.*
DICOM server/visualizer dedicated to PC	*ESA-VIEW Rel.1*	*ESA-VIEW Rel.2*	*ESA-VIEW Rel.2 is a DICOM server/visualizer dedicated to Personal Computers and is part of the DICOMed family of products. It is picture archiving and communications system software that provides acquisition, storage, transfer, and display of medical image data.* *The DICOMed family is a class II device in accordance with 21CFR892.2050 - Federal Register 01/04/01 and was cleared via K012093.*

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

AUG 13 2003

Esaote, S.p.A.
% Ms. Colleen J. Densmore
The Anson Group LLC
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K032121
Trade/Device Name: E-Scan XQ MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: July 8, 2003
Received: July 14, 2003

Dear Ms. Densmore:

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

Indications for Use

510(k) Number (if known): K032121

Device Name: _____

Indications for Use:

E-scan XQ is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross–section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging portions of the leg, including the foot, ankle, calf, knee, thigh and hip.

E-scan XQ MR 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 ✓

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032121

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

Concurrence of CDRH, Office of Device Evaluation (ODE)