MAY - 4 2004

510(k) Summary

K040877

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 2, 2004

807.92(a)(2)

Trade Name: C-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)

Esaote	Artoscan C	K010057

801.92(a)(4)

Device Description

Summary of C-Scan modifications
The changes performed on the C-scan device, with respect to the cleared version – Artoscan C K010057 –, are due to the improvement of the system performance. These modifications do not affect the intended use or alter the fundamental scientific technology of the device and are the following:

1. Upgrading of the electronics.
2. New pulse sequences.
3. A new software release.
4. Mobile installation.

System configuration

Unmodified Artoscan C
The system is composed of three main parts:
1. Patient Positioning Seat
2. Operating console that consists of the PC unit (including keyboard and mouse), the monitor and the operating table.
3. Electronics and Magnetic Unit

Modified C-scan
The system is composed of three main parts:
1. Patient Positioning Seat
2. Operating console that consists of the PC unit (including keyboard and mouse), the monitor and the operating table.
3. Electronics and Magnetic Unit

807.92(a)(5)

Intended Use(s)

C-scan 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 and elbow, but excluding the upper arm, and imaging portions of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

C-scan 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.

Comparison to the cleared device
Artoscan C K010057

Imaging system

Characteristics	Artoscan C K010057	C-scan	Comments
Pulse sequences	Orthogonal Multi-planar Scout Spin Echo T1 (SET1) Spin Echo T2 (SET2) Multiple Spin-Echo (SE_PD_T2) Inversion Recovery (IR) Short TI Inversion Recovery (STIR) Gradient Echo (GE) Gradient Echo 3D (GE3D) Gradient Echo 3D contrast enhancement (3DCE) Half Echo T1-weighted Spin Echo (SET1HE) Half Fourier T1-weighted Spin Echo (SET1HF) Turbo SE T2 weighted and Turbo ME (TSE, TME) Turbo 3D T1 isotropic and anisotropic (T3D_T1) Short Time Inversion Recovery Gradient Echo (GE_STIR) Real Time	Orthogonal Multi-planar Scout Spin Echo T1 (SET1) Spin Echo T1 3D (SET1_3D) Spin Echo T2 (SET2) Multiple Spin-Echo (SE_PD_T2) Inversion Recovery (IR) Short TI Inversion Recovery (STIR) Short TI Inversion Recovery 3D (STIR_3D) Gradient Echo (GE) Gradient Echo 3D (GE_3D) Gradient Echo 3D contrast enhancement (3DCE) Half Echo T1-weighted Spin Echo (SET1HE) Half Fourier T1-weighted Spin Echo (SET1HF) Turbo SE T2 weighted and Turbo ME (TSE, TME) Turbo 3D T1 isotropic and anisotropic (T3D_T1) Short Time Inversion Recovery Gradient Echo (GE_STIR) Short Time Inversion Recovery Gradient Echo (GE_STIR_3D) Real Time	The new sequences are described in the section "Device modification description".
Sequence parameters		set1_3D TR from 60 ms to 5000 ms step 20 ms TE =24 ms minimum FOV 100 mm	See section "Device modification description".

Characteristics	Artoscan C K010057	C-scan	Comments
		FOV 3D (vol. thickness) from 40 to 200 mm step 10 mm <u>stir_3D</u>: TR from 150 ms to 5000 ms step 10 ms TE = 24 ms TI from 20 ms to 200 ms, step 5 ms minimum FOV 100 mm FOV 3D (vol. thickness) from 40 to 200 mm step 10 mm <u>ge_stir_3D:</u> TR from 150 ms to 5000 ms step 10 ms TE = 16 ms TI from 20 ms to 200 ms, step 5 ms FA = 90° minimum FOV 100 mm FOV 3D (vol. thickness) from 40 to 200 mm step 10 mm <u>ge_stir_25:</u> TR from 150 ms to 5000 ms step 10 ms TE = 25 ms TI from 20 ms to 200 ms, step 5 ms FA = 90° minimum FOV 130 mm minimum thickness = 3 mm <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	This is an optimized ge_stir sequence with a fixed TE, in order to maximize the Signal to Noise ratio (already present on E-scan XQ K032121). The high resolution sequences are a particular version of the Artoscan C 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

Characteristics	Artoscan C K010057	C-scan	Comments
		minimum FOV 100 mm minimum slice thickness 2.0 mm <u>High Resolution se_18_he</u> 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 <u>High Resolution tse_80:</u> 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 <u>High Resolution tme:</u> 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 <u>High Resolution ge_16:</u> 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	with TE=26 msec. 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 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. All the high resolution sequences are already present on E-scan XQ K032121.
Acquisition Matrix:	2D FT: from 192x 128 to 256x256; phase encoding step 8 3D FT: from 192x128 to 256x256;	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	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)

Characteristics	Artoscan C K010057	C-scan	Comments
	slice encoding from 24 to 128, step 8; phase encoding step 8	encoding step 8	sampling points and the number of phase encoding steps.
Spatial Resolution:	Up to 0.4 mm (nominal value)	Up to 0.2 mm (nominal value)	Spatial resolution is the ability to distinguish two points as separate and distinct. The nominal spatial resolution coincides with the minimum pixel size: min pixel size = min FOV / max matrix size = 100 x 100 mm / 512 x 512

Gradients System

Characteristics	Artoscan C K010057	C-scan	Comments
Control System:	Digital, based on DSP SHARC 21062 @ 40 MHz, 80 MFLOPs, with 256 KB On-Chip SRAM 3 independent channels (X-Y-Z) DAC 18 bit - updating every 7.2 µs Hardware ramp generation – hardware pre-emphasis of eddy current compensation	Digital electronic, based on DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM 3 independent channels (X-Y-Z) DAC 18 bit – update every 7.2 µs Software ramp generation – software pre-emphasis of eddy current suppression	The new control system is described in the section "Device Modification Description"
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 (50/60 Hz - 16.6. Hz) Digital electronic based on microcontroller HC11.*	*"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. Digital electronic, based on DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM*	Technological updating. A more detailed decription is in the the section "Device modification description".

Radiofrequency System

Characteristics	Artoscan C K010057	C-scan	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. Transferring to DSPM of raw data real and imaginary parts.	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, 1°.19 phase stability : < 1 ppm into the operative temperature range; $\leq 8 \times 10^{-8}$ on 15 minutes (maximum variation 0,75°C) transmission variable gain: 256 levels	Technological updating. A more detailed decription is in the the section "Device modification description".

Image Processing and Display System

Characteristics	Artoscan C K010057	C-scan	Comments
Central Processing Unit	ISA and PCI Bus CPU Pentium III 700 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

Characteristics	Artoscan C K010057	C-scan	Comments
Control processor	DSP SHARC 21062 @ 40 MHz, 80 MFLOPs, with 256 KB On-Chip SRAM	DSP SHARC 21161@100 MHz, 400 MFLOPs, 128 KB On-Chip SRAM + 384 KB SSRAM	Technological updating
Acquisition and reconstruction processor:	DSP SHARC 21060 @ 40 MHz, 80 MFLOPs, with 512 KB On-Chip SRAM + 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.

Installation Area Conditions

Characteristics	Artoscan C K010057	C-scan	Comments
Type of installation:	Permanent	Permanent, Mobile	The mobile installation is described in the section "Device modification description".

Power supply

Characteristics	Artoscan C K010057	C-scan	Comments
Power consumption:	1100 VA during quick magnet heating 600 VA during normal working 150 VA when unit is powered off (thermal control on)	950 VA during quick magnet heating 600 VA during normal working 150 VA when unit is powered off (thermal control on)	More precise characterization of the data.

Note: Any deviations from original Artoscan C 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

MAY - 4 2004

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

Re: K040877
Trade/Device Name: C-scan MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: April 2, 2004
Received: April 5, 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 (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 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): K040877

Device Name: C-scan MR System

Indications for Use:

C-scan 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 and elbow, but excluding the upper arm, and imaging portions of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

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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)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040877