

JUL 13 1998

K981358

Safety and Effectiveness Summary
Artoscan S
Biosound Esaote

Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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FDA/CDRH/ODE/DMC

807.92(a)(2)

Trade Name: Artoscan S
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
Hitachi	AIRIS	K945155
Elscint	PRIMA 1TG	K970990

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

1. Imaging System

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
Clinical use	Knee, leg, ankle, foot, hand, wrist, forearm, elbow, shoulder, hip.	Whole body, central nervous system and orthopaedic regions.	Two new joints (hip and shoulder) have been introduced for examination.
Field of view	From 100 up to 300 mm, step 10 mm (140 mm are displayed).	From 50 up to 350 mm in diameter.	A larger FOV has been realized to better cover the anatomical parts to be imaged.

1. Magnetic System

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
Type of magnet	"C" shaped Neodymium alloy permanent magnet.	"C" shaped Neomax™ (Neodymium alloy) permanent magnet.	
Static field strength	0.18 T (perpendicular to patient's body).	0.3 T (perpendicular to patient's body).	
Fringe field	5 G line at 1.4 m maximum from the centre of the magnet.	5 G line at 2.5 m maximum from the centre of the magnet.	
Gantry opening	620 mm x 240 mm (w x h)	1000 x 380 mm(w x h)	
Magnetic system weight	1700 kg	10000 kg	

1. Radiofrequency System

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
Solenoidal receiver coils	Shoulder/Knee Coil 17.5x7.6x14.7 cm Hip Coil 20 x 23 x 14 cm (internal dimensions: w x d x h)	Large joint Coil (shoulder, knee) 18.4x23 cm wxh Flexible body Coil (hip and other regions) 20x150 cm wxd	The technology of the solenoidal (or linear) coils is unchanged compared to the technology used for the ARTOSCAN M coils. Coils with different shapes

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
			have been developed to adapt to the geometrical characteristics of the gantry and to the new limbs to examine.
RF power	up to 600 W peak pulse	up to 5000 W peak pulse	

1. Patient Positioning

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
Patient comfort	The large magnet opening and the device design, that allows the patient to be almost completely out of the magnet, except the examined portion, virtually eliminate claustrophobia and other related reactions during the examination.	The large magnet opening virtually eliminates the anxiety and claustrophobia often experienced by patients in the narrow bore of conventional MR imaging systems.	
Patient positioning	An adjustable couch is used to position the patient's limb inside the gantry. The couch is pushed into the gantry manually.	An adjustable motorized table is used to position the patient inside the gantry.	The same positioning philosophy as ARTOSCAN M, suitable for the new gantry shape, has been used for ARTOSCAN S.

1. Installation Area Conditions

Characteristic	ARTOSCAN S	AIRIS K945155	Comments
Area necessary	3.7 m x 3.7 m	4 m x 5 m (gantry and patient table) 4 m x 2.5 m (operator console, MRI unit and other components)	
RF shielding	Self contained RF shielding (up to 30 dB μ V/m). External shielding (up to 100 dB μ V/m).	The scan room must be RF shielded to 60 dB. RF noise inside the scan room should meet 0.5+30 MHz, 0 dB μ V/m or less.	

2. Magnetic System

Characteristic	ARTOSCAN S	PRIMA 1TG K970990	Comments
Gradient strength	20 mT/m	<u>whole-body set</u> 21 mT/m	With higher gradient strength it is possible to minimize at the same time FOV and slice thickness, also for sequences with very short TE, improving the spatial resolution.
Rise time	0.5 msec from 0 to 20 mT or from -20 to 0 mT	0.5 msec to full amplitude <u>supplementary set</u> 30 mT/m 0.41 msec to full amplitude	

3. Imaging System

Characteristic	ARTOSCAN S	ARTOSCAN M K963262	Comments
Data acquisition modes	Spin warp 2D/3D Half Scan Half Echo	Spin warp 2D/3D Half Scan Half Echo	Unchanged
Pulse sequences	Multiplanar Ortho-Scout T1-weighted Spin Echo (SET1) T2-weighted Spin Echo (SET2) Multiple Spin-Echo (MEDE) Gradient Echo (GE) Inversion Recovery (IR) Short TI Inversion Recovery (STIR) Half Echo T1-weighted Spin Echo (SET1HE) Half Fourier T1-weighted Spin Echo (SET1HF) Turbo T2-weighted Spin-Echo (TSE) Turbo Multiple Spin-Echo (TME) Turbo Gradient Echo (TGE) 3D Gradient Echo (GE3D) Turbo 3D T1-weighted Gradient Echo (T3D_T1) Turbo 3D T2-weighted Gradient Echo (T3D_T2) Short TI Inversion Recovery Gradient Echo (GEFS) Magnetization Transfer (GEMT) 3D Magnetization Transfer (GE3DMT)	Multiplanar Ortho-Scout T1-weighted Spin Echo (SET1) T2-weighted Spin Echo (SET2) Multiple Spin-Echo (MEDE) Gradient Echo (GE) Inversion Recovery (IR) Short TI Inversion Recovery (STIR) Half Echo T1-weighted Spin Echo (SET1HE) Half Fourier T1-weighted Spin Echo (SET1HF) Turbo T2-weighted Spin-Echo (TSE) Turbo Multiple Spin-Echo (TME) Turbo Gradient Echo (TGE) 3D Gradient Echo (GE3D) Turbo 3D T1-weighted Gradient Echo (T3D_T1) Turbo 3D T2-weighted Gradient Echo (T3D_T2) Short TI Inversion Recovery Gradient Echo (GEFS) Magnetization Transfer (GEMT) 3D Magnetization Transfer (GE3DMT)	Unchanged
Slice thickness	2D FT: from 2 mm to 10 mm, step 0.5 mm 3D FT: from 0.6 mm to 10 mm, step 0.1 mm	2D FT: from 2 mm to 10 mm, step 0.5 mm 3D FT: from 0.6 mm to 10 mm, step 0.1 mm	Unchanged
Interslice spacing	Not necessary: contiguous slicing is available	Not necessary: contiguous slicing is available	Unchanged

Characteristic	ARTOSCAN S	ARTOSCAN M K963262	Comments
Slice orientation	Transverse Sagittal Coronal Oblique Multislice packages	Transverse Sagittal Coronal Oblique Multislice packages	Unchanged
Acquisition matrix	2D FT: from 192x128 up to 256x256; phase encoding step 8 3D FT: from 192x128 up to 256x256; slice encoding from 8 to 128, step 8; phase encoding step 8	2D FT: from 192x128 up to 256x256; phase encoding step 8 3D FT: from 192x128 up to 256x256; slice encoding from 8 to 128, step 8; phase encoding step 8	Unchanged
Spatial resolution	Up to 0.4 mm.	Up to 0.4 mm.	Unchanged
Multi-slice	128 slices max (for each echo)	128 slices max (for each echo)	Unchanged
Multi-echo	2 echoes max	2 echoes max	Unchanged
Scan parameters	<u>TR</u> SET1: 50 ~ 5000 ms, step 10 ms SET2: 200 ~ 5000 ms, step 10 ms MEDE: 200 ~ 5000 ms, step 10 ms GE: 60 ~ 5000 ms., step 10 ms IR: 260 ~ 5000 ms, step 10 ms STIR: 100 ~ 5000 ms, step 10 ms SET1HE: 50 ~ 5000 ms, step 10 ms SET1HF: 50 ~ 5000 ms, step 10 ms TSE: 200 ~ 5000 ms, step 10 ms TME: 200 ~ 5000 ms., step 10 ms TGE: 30 ~ 5000 ms, step 5 ms GE3D: 40 ~ 5000 ms, step 10 ms T3D_T1: 25 ~ 5000 ms, step 5 ms	<u>TR</u> SET1: 50 ~ 5000 ms, step 10 ms SET2: 200 ~ 5000 ms, step 10 ms MEDE: 200 ~ 5000 ms, step 10 ms GE: 60 ~ 5000 ms., step 10 ms IR: 260 ~ 5000 ms, step 10 ms STIR: 100 ~ 5000 ms, step 10 ms SET1HE: 50 ~ 5000 ms, step 10 ms SET1HF: 50 ~ 5000 ms, step 10 ms TSE: 200 ~ 5000 ms, step 10 ms TME: 200 ~ 5000 ms., step 10 ms TGE: 30 ~ 5000 ms, step 5 ms GE3D: 40 ~ 5000 ms, step 10 ms T3D_T1: 25 ~ 5000 ms, step 5 ms	Unchanged

Characteristic	ARTOSCAN S	ARTOSCAN M K963262	Comments
	T3D_T2 : 35 ~ 5000 ms, step 1 ms GEFS: 70 ~ 5000 ms., step 10 ms GEMT: 40 ~ 5000 ms, step 5 ms GE3DMT: 45 ~ 5000 ms, step 5 ms	T3D_T2 : 35 ~ 5000 ms, step 1 ms GEFS: 70 ~ 5000 ms., step 10 ms GEMT: 40 ~ 5000 ms, step 5 ms GE3DMT: 45 ~ 5000 ms, step 5 ms	
	<u>TE</u> SET1: 16 ~ 34 ms, step 2 ms SET2: 80 ~ 120 ms, step 10 ms MEDE: 1st echo 38 ms; 2nd echo 90 ms GE: 12 ~ 24 ms, step 2 ms IR: 16 ~ 34 ms, step 2 ms STIR: 16 ~ 34 ms, step 2 ms SET1HE: 10 ~ 24 ms, step 2 ms SET1HF: 16 ~ 34 ms, step 2 ms TSE: 80 ~ 120 ms, step 10 ms TME: 1st echo 38 ms; 2nd echo 90 ms TGE: 8 ~ 24 ms, step 1 ms GE3D: 8 ~ 24 ms, step 1 ms T3D_T1: 8 ~ 24 ms, step 1 ms T3D_T2 : fixed at 16 ms GEFS: 8 ~ 24 ms, step 1 ms GEMT: 8 ~ 24 ms, step 1 ms GE3D MT: 8 ~ 24 ms, step 1 ms	<u>TE</u> SET1: 18 ~ 34 ms, step 2 ms SET2: 80 ~ 120 ms, step 10 ms MEDE: 1st echo 38 ms; 2nd echo 90 ms GE: 12 ~ 24 ms, step 2 ms IR: 18 ~ 34 ms, step 2 ms STIR: 18 ~ 34 ms, step 2 ms SET1HE: 12 ~ 24 ms, step 2 ms SET1HF: 18 ~ 34 ms, step 2 ms TSE: 80 ~ 120 ms, step 10 ms TME: 1st echo 38 ms; 2nd echo 90 ms TGE: 8 ~ 24 ms, step 1 ms GE3D: 14 ~ 24 ms, step 2 ms T3D_T1: 8 ~ 24 ms, step 1 ms T3D_T2 : fixed at 16 ms GEFS: 12 ~ 24 ms, step 2 ms GEMT: 8 ~ 24 ms, step 1 ms GE3D MT: 8 ~ 24 ms, step 1 ms	The sequences are substantially unchanged. For some sequences we used shorter TE, to obtain a more T1- weighted contrast. That is possible thanks the higher gradient strength.
	<u>TI</u> IR: 200 ~ 800 ms, step 10 ms STIR: 50 ~ 200 ms, step 5 ms	<u>TI</u> IR: 200 ~ 800 ms, step 10 ms STIR: 50 ~ 200 ms, step 5 ms	Unchanged

Characteristic	ARTOSCAN S	ARTOSCAN M K963262	Comments
	GEFS : 20 ~ 200 ms, step 5 ms	GEFS : 20 ~ 200 ms, step 5 ms	
	FA GE: fixed at 90° TGE: 10° ~ 90°, step 5° GE3D: 10° ~ 90°, step 5° T3D_T1: 10° ~ 90°, step 5° T3D_T2 : fixed at 90° GEFS : fixed at 90° GEMT: 10° ~ 90°, step 5° GE3DMT: 10° ~ 90°, step 5°	FA GE: fixed at 90° TGE: 10° ~ 90°, step 5° GE3D: 10° ~ 90°, step 5° T3D_T1: 10° ~ 90°, step 5° T3D_T2 : fixed at 90° GEFS : fixed at 90° GEMT: 10° ~ 90°, step 5° GE3DMT: 10° ~ 90°, step 5°	Unchanged

3. Radiofrequency System

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
DPA receiver coils	DPA Knee Coil 14.2x17.8x15.8 cm DPA Ankle Coil 8.7x21.4x14.6 cm DPA Hand/Wrist Coil 7.2x18.6x11.9 cm (internal dimensions: w x d x h)	DPA Knee Coil 12.5x19.3x13.7 cm DPA Ankle Coil 8.7x21.4x14.6 cm DPA Hand/Wrist Coil 7.2x18.6x11.9 cm (internal dimensions: w x d x h)	The technology of the DPA (or quadrature) coils is unchanged compared to the technology used for the ARTOSCAN M coils. A more comfortable knee coil has been developed.

3. Image Processing and Display System

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
Central processing unit	CPU: Pentium 200 MHz Main memory: 32 MB; 256 KB cache memory	CPU: Pentium 200 MHz Main memory: 32 MB; 256 KB cache memory	Unchanged
Control processor	16.7 MIPS, 0.5 MB memory	16.7 MIPS, 0.5 MB memory	Unchanged
Acquisition and reconstruction processor	33 MFlops, 65 MB memory	33 MFlops, 65 MB memory	Unchanged
Hard disk unit	3 ¹ / ₂ ; 2.6 GB	3 ¹ / ₂ ; 2.6 GB	Unchanged

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
Rewritable optical disk unit	3 ¹ / ₂ , R/W, 640 MB, 1 side	3 ¹ / ₂ , R/W, 640 MB, 1 side	Unchanged
Image reconstruction time	<u>2D</u> 1 sec/img in Format1 with visualization 0.8 sec/img in Format4 with visualization <u>3D</u> ≈ 35 sec for reconstructing a 256x256x128 data cube, to calculate the three Scout images and to save the image cube (256x256x128, 8 bit/pixel)	<u>2D</u> 1 sec/img in Format1 with visualization 0.8 sec/img in Format4 with visualization <u>3D</u> ≈ 35 sec for reconstructing a 256x256x128 data cube, to calculate the three Scout images and to save the image cube (256x256x128, 8 bit/pixel)	Unchanged
Display matrix	Format1: 510x478; Format4: 254x238;	Format1: 510x478; Format4: 254x238;	Unchanged
Grey scale	4096 (0+4095) Grey levels in 2D 256 Grey levels in 3D	4096 (0+4095) Grey levels in 2D 256 Grey levels in 3D	Unchanged
Display monitor	17" Colour 640x480 pixel, 60 Hz non-interleaved, high contrast	17" Colour 640x480 pixel, 60 Hz non-interleaved, high contrast	Unchanged The DHHS Accession Number is: 9531534-07.
Image filtering	Automatic image filtering in visualization by an adaptive filter, depending on the image acquisition parameters characterizing the image to be filtered. Non-automatic image filtering by three types of adaptive filters and two types of non-adaptive filters.	Automatic image filtering in visualization by an adaptive filter, depending on the image acquisition parameters characterizing the image to be filtered. Non-automatic image filtering by three types of adaptive filters and two types of non-adaptive filters.	Unchanged
Networking functions	Printing of images that have been pre-formatted in DICOM3 protocol form. Sending images in DICOM3 protocol form using TCP/IP. Sending images to other systems of the	Printing of images that have been pre-formatted in DICOM3 protocol form. Sending images in DICOM3 protocol form using TCP/IP. Sending images to other systems of the	Unchanged

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
	ARTOSCAN-Dedicated MRI family using TCP/IP or PPP (Modem).	ARTOSCAN-Dedicated MRI family using TCP/IP or PPP (Modem).	

3. Patient positioning

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
Limb fastening	All coils are especially designed to keep the examined limb in the proper position.	All coils are especially designed to keep the examined limb in the proper position.	Unchanged

3. Installation Area Conditions

Characteristic	ARTOSCAN S	ARTOSCAN M	Comments
Type of installation	Fixed area ("permanently installed" according to EN 60601-1)	Fixed area ("permanently installed" according to EN 60601-1) Mobile	Differently from ARTOSCAN M, ARTOSCAN S has not a mobile configuration.

Note: Any deviations from original ARTOSCAN M specifications are substantiated within Quality System documentation at Esaote S.p.A..



JUL 13 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Colleen Hittle
Official Correspondent
Biosound Esaote, Inc.
8000 Castleway Drive
Indianapolis, IN 46250Re: K981358
Artoscan S (MRI System)
Dated: April 13, 1998
Received: April 14, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LHN

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K981358

Device Name: Artoscan S

Indications for Use:

The Artoscan S is intended for diagnostic nuclear magnetic resonance imaging of the hip, leg, knee, ankle, foot, shoulder, elbow, forearm, wrist and hand. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981358