

MAR 28 1997

K963262

MAR 28 1997

## Safety and Effectiveness Summary

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

807.92(a)(1)

### Submitter Information

Wayne Nethercutt Director, Regulatory Affairs

7990 Castleway Drive

Indianapolis, IN 46250

Phone: (317) 849-1793

Facsimile: (317) 841-8616

Contact Person: Wayne Nethercutt

Date: 08-16-96

807.92(a)(2)

Trade Name: ARTOSCAN M

Common Name: Magnetic Resonance Imaging Device

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

Classification Number: 892.1000

807.92(a)(3)

**Predicate Device(s)**

- |                            |                                |
|----------------------------|--------------------------------|
| • Esaote ARTOSCAN K931022  | MRI Device Corp. K931008       |
| • Hitachi MRP-7000 K911667 | Medical Advances, Inc. K934396 |
| • Siemens Magnetom K935661 | Hitachi NW 5000 K911642        |
| • Philips Gyroscan K940534 | Resonex Kinematic MRI K924154  |
| • Magna Lab K940849        | Hitachi Mobile NW 7000 K920159 |

Additional Substantial Equivalence information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4)

**Device Description**

ARTOSCAN M is an MRI system designed specifically to image the extremities: leg (thigh excluded), knee, ankle and foot, forearm, elbow, wrist and hand. A number of modifications have been designed to enhance the functioning of the ARTOSCAN system previously cleared under K931022. The modifications will collectively be referred to as the ARTOSCAN M. Once the modifications described herein are cleared, the ARTOSCAN M will be marketed in place of the original ARTOSCAN device. The difference in the name is very subtle and consists of adding an M after the ARTOSCAN name. Existing ARTOSCAN units (original configuration) can be upgraded to the ARTOSCAN M if the user so desires.

No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act. The equipment complies with **EN 60601 - 1, EN 60601-1-1, IEC 601-2-33, EN 60601-1-2**. The equipment is certified according to **MDD 93/42/EEC (CE mark)**. ESAOTE meets the quality standard requirements of , **UNI EN ISO 9001 (CISQ CSQ 9120.ESOI)** and **UNI CEI EN 46001 (CISQ CSQ Nffid 9124.ES03)**. All phases regarding design, prototyping, manufacturing, quality tests, etc. related to ARTOSCAN M and ARTOSCAN upgrades are performed according to the above mentioned requirements. Safety parameters are measured following the **IEC 601-2-33** rules. Imaging performance parameters are measured following the proper **NEMA** standard methods.

#### Summary of ARTOSCAN M Features:

- A modular structure allows a great flexibility in location.
- A compact magnet, specifically designed for the NM imaging of limbs, provides the power and field uniformity required for quality imaging with a negligible fringe field.
- An Integrated Faraday Cage eliminates any need for external shielding.
- A unique coupling between gantry and coils provides an accurate Self-Centering Mechanism. The self-centering coils optimize imaging and restrict involuntary limb movements.
- For examination of knees and wrists under dynamic and stress conditions, special Cinematic Devices are provided.
- The ARTOSCAN M user interface is simple and very complete. For routine limb studies, pre-defined imaging protocols guide the user in optimizing scan parameters and minimize operator training. The ARTOSCAN software provides all standard image acquisition and processing functions in a user- friendly format.
- The patient is outside of the gantry, except for limb being examined, thus enhancing patient comfort and eliminating any claustrophobic reaction.

#### 807.92(a)(5)

##### **Intended Use(s)**

The ARTOSCAN M is intended for diagnostic nuclear magnetic imaging of the knee, leg, ankle, foot, hand, wrist forearm and elbow. The device produces transverse, sagittal, coronal and oblique cross-sectional images displaying the internal structure of the anatomy being imaged.

## Substantial Equivalence Comparison Table

Characteristics	Imaging System		Comments
	ARTOSCAN	ARTOSCAN M	
Clinical use	Knee, leg, ankle, foot hand wrist, forearm, elbow	Knee, leg, ankle, foot, hand wrist, forearm, elbow	Unchanged
Data acquisition modes	Spin warp 2D/3D	Spin warp 2D/3D <i>Half Scan</i> <i>Half Echo</i>	Two further acquisition modes are now included: the Half Scan mode allows to speed up the acquisition time while the Half Echo mode permits to shorten the echo time and improve the image contrast. Both techniques are universally known by the literature and used on commercial MRI scanners. See for instance the Hitachi MRP-7000 (K911667)
Pulse sequences	<p>Multiplanar Ortho- Scout Spin Echo (SE)</p> <p>Multiple Spin-Echo (ME) Gradient Echo (GRE)</p> <p>Inversion Recovery (IR)</p>	<p>Multiplanar Ortho-Scout T1-weighted Spin Echo T2-weighted Spin Echo (SET2) Multiple Spin-Echo (ME) Gradient Echo (GRE - GRE3D) Inversion Recovery (IR)</p> <p>Short TI Inversion Recovery (STIR)</p> <p><i>Half Echo T1-weighted SE (SETIHE)</i></p> <p><i>Half Fourier T1-weighted SE (SET1HF)</i></p>	<p>The set of available sequences has been enlarged to cover what is now usually offered on standard MRI systems and is required by physicians to improve their clinical activity.</p> <p>The STIR sequence is an FR sequence, where the minimum TI is 50 ms, providing fat-suppressed T1- weighted images</p> <p>SE sequence using the Half Echo technique aimed at obtaining strongly T1- weighted images</p> <p>SE sequence using the Half Fourier technique aimed at reducing the acquisition time</p>

## Imaging System

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
		<i>Turbo T2-weighted SE (TSE)</i> <i>Turbo ME (TME)</i>	TSE and TME are based on the Half Fourier technique, therefore are quicker than the standard SE and ME sequences. The Half Fourier technique and the contribution of different echoes are optimized to obtain proton density and T2weighted images. The contrast provided by those sequences is equivalent to the contrast provided by standard proton density and T2weighted sequences. See Siemens Magnetom Open (K935661)
		<i>Turbo GRE (TGRE)</i> standard GRE	This is an optimized version of the
		<i>Turbo GRE3D (TGRE3D)</i>	The TGRE3D sequence is an optimized version of the GRE3D. See Philips Gyroscan T I O-NT where the technique is mentioned as Kspace shutter (K940534)
		<i>Magnetization Transfer Contrast</i> <i>(MT GRE, MT GRE3D)</i>	The MT allows to change the contrast provided by any sequence. In particular, with regard to articular applications, it allows to increase the contrast fat/muscle and cartilage/synovia. MT is available on other commercial MR scanners, typically for angiographic applications, like for instance Philips Gyroscan TIO-T(K940534).
		<i>Fat Suppression (FS)</i>	The FS sequence uses the 3 points Dixon technique. It is available on Advanced Mammography System AURORA (K950837)

**General**

<b>Characteristics</b>	<b>ARTOSCAN</b>	<b>ARTOSCAN M</b>	<b>Comments</b>
Patient comfort	The patient is completely out of the magnet, except the examined portion, eliminating claustrophobia and other related reactions during the examination	The patient is completely out of the magnet, except the examined portion, eliminating claustrophobia and other related reactions during the examination	
<i>Network capability(optional)</i>	<i>Ethernet local network</i>	<ul style="list-style-type: none"> <li>* <i>Ethernet thin wire local connection through DICOAF protocol</i></li> <li>* <i>Ethernet thin wire local connection through TCPIIP protocol</i></li> <li>* <i>Remote connection through modem</i></li> </ul>	With the present release, the DICOM protocol is available (at the moment DICOM is the most accredited communication standard) and both local and remote connections are provided.
<i>Additional console (optional)</i>	n.a.	<i>Includes all the image processing functions available on the main system. Configuration: CPU.- Pentium I 00 Mhz Main memory: 32 MR 3-1/4 " Hard disk: 2 GB</i>	
Type of installation	Fixed site ("Permanently installed" according to IEC 601-1)	Fixed site ("Permanently installed" according to IEC 601-1) Mobile	ARTOSCAN and ARTOSCAN M may be installed also as mobile systems. See for instance HITACHI Mobile NW-7000 (K920159)

### Imaging System

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
Scan parameters:	TR: SE: 50 - 5000 ms. IR: 200 -5000 ms GRE: 40 - 5000 ms	TR SET 1 50 - 5000 ms., step 10 ms SET2: 200 - 5000 ms., step 10 ms NE: 200 - 5000 ms., step 10 ms GRE: 40 - 5000 ms., step 10 ms GRE3D: 40 - 5000 ms., step 10 ms IR: 260 - 5000 ms., step 10 ms STIR: 90 - 5000 ms., step 10 ms SETIHE: 50 - 5000 ms., step 10 ms SETIHF- 50 - 5000 ms., step 10 ms TSE: 200 - 5000 ms., step 10 ms 200 - 5000 ms., step 10 ms TGRE: 30 - 5000 ms., step 5 ms TGRE3D: 30 - 5000 ms., step 5 ms MTGRE: 50 - 5000 ms., step 10 ms MTGRE3D: 50 - 5000 ms., step 10 ms FS: 70 - 5000 ms., step 10 ms STIR-GRE: 40 - 5000 ms., step 10 ms	Parameters have been optimized.
	TE SE: 18, 21, 26, 40, 80, 120,150 ms GRE: 10 ms	TE SET1: 18 -34 ms., step 2 ms SET2: 80 - 120 ms., step 10 ms Nffi: 1 st echo 40 ms; 2nd echo 80 and 100 ms GRE: 12 - 24 ms., step 2 ms GRE3D: 14 - 24 ms., step 2 ms IR: 18 - 34 ms., step 2 ms STIR: 18 - 34 ms., step 2 ms SET UM: 12 - 24 ms., step 2 ms SET I HF: 18 - 34 ms., step 2 ms TSE: 80 - 120 ms., step 10 ms 1st echo 34 ms; 2nd echo 90 Ms TGRE: 8 - 24 ms., step 1 ms TGRE3D: 8 - 24 ms., step 1 ms MT-GRE: 12 - 24 ms., step 2 ms MT-GRE3D: 14 - 24 ms., step 2 ms FS: 30 ms STIR-GRE: 12 - 24 ms., step 2 ms	

## Imaging System

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
	<p><u>TI</u> IR: 100 - 800 ms</p> <p><u>FA</u> GRE: 10°- 90°</p>	<p><u>TI</u> IR: 200 - 800 ms., step 10 ms STIR: 50 - 200 ms., step 5 ms STIR-GRE: 50 - 200 ms., step 5 Ms</p> <p><u>FA</u> GRE: 10° - 120°, step 5' GRE3D: 10° - 120°, step 5' MT GRE: 10°- 120°, step 5' M'CGRE3D: 10° - 120°, step 5- TGRE: 10° - 90°, step 5' TGRE3D: 10°- 90°, step 5' STIR-GRE: 10° - 120°, step 5'</p>	
Receiver coils	<p>Solenoidal coils Lowerjoint: 16x18 cm 0 Lower joint (that can be opened): 14 cm 0 Ankle (that can be opened): 12x 16 cm 0 Upperjoint: 10 cm 0</p>	<p>Solenoidal coils Large knees: 14.5x 19 cm 0 Knee/Ankle: 13. 1x 14.5 cm 0 Upperjoint: 12 cm 0 examination. <i>Quadrature coils (optional)</i> <i>Han Wrist: 8x 11.5x14.5 cm</i> <i>Ankle/Foot.- 9.5x15x23 cm 0</i> <i>Knee: 12.9x14.5x15.5 cm 0</i></p>	<p>Solenoidal coils have been changed a little bit in size and design to better fit the anatomic regions under</p> <p>No coils that can be opened are present in the actual version because of the easiness in positioning the standard coils. <u>Quadrature coils, usually present on most of commercial NMI scanners, have been included to further increase the S/N ratio and the image quality on the whole.</u> See for instance MRI Devices Corp. - QD wrist and hand coil (K931008) and Medical Advances, Inc. - QD Lower extremity coil (K934396) All the new coils may be automatically identified through a clutch system, so avoiding possible mistakes in the setup session.</p>

## Image Processing / Display System

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
Central processing unit	CPU: 486 33 MHz 256 KB cache memory Main memory: 16 MB; 5-1/4" Hard disk: 650 MB Control processor: 12.5 MIPS - 0.5 NM on board Digital Signal Processor: 25 Mflops - 0.7 MB on board	CPU: Pentium 100 MHz Main memory: 32 MB; 512 KB cache memory 3-1/4" Hard disk: 2 GB Control processor: 16.7 MIPS 0.5 NM on board Digital Signal Processor: 33 Mflops * 5 MB on board (standard configuration) * 65 MB on board (optional)	Improved
Optical disk	5-1/4" R/W 650 MB (optional)	5-1/4" R/W 1.3 GB (optional)	Improved
Monitor	15" B/W 640x480	15" B/W 640x480	Unchanged
Gray scale	4096 gray levels (O. 4095)	4096 gray levels (O. 4095)	Unchanged
Image reconstruction time (256x256)	1.5 sec./img simultaneous display is possible (+ 1.3 sec. to display a 512x512 image or + 0.4 sec. to display a 256x256 image)	<u>2D</u> 1.4 sec./img simultaneous display is possible (+ 1 sec. to display a 512x512 image or + 0.3 sec. to display a 256x256 image) <u>3D</u> ≈3 min. for reconstructing a 192x160x96 volume, reslicing three scout images and saving the volume (256x256x96 bit/voxel) ≈30 sec. with the 3D Turbo option enabled	Improved. In the present release, 3D raw data may be saved and permanently stored to be resliced later, even from a different console.
Display matrix	510x478,254x239	510x478,254x238	Unchanged
Image filtering	Edge enhancement (Off-line) Noise cleaning (Off-line)	<i>Adaptive filters (optional). In case the user chooses the on-line option, a specific filter in two variants (internally named A and B) may be applied automatically by the system, according to the acquisition parameters characterizing the image to be filtered. The other way they may be applied off-line by the user when desired. In this case, the original images are always at the user's disposal for possible comparisons.</i>	The present filters are part of the most recent filtering packages to improve the image quality. They underwent a validation protocol carried out by clinical users, that ended with positive results.

### Magnetic / Gradients System

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
Type of magnet	Ferrite permanent magnet	Ferrite permanent magnet	Unchanged
Static field strength	0.18T (transversal)	0.18T (transversal)	Unchanged
Stray field	5G line at 65 cm maximum from the magnet	5G line at 65 cm maximum from the magnet	Unchanged
Gradients strength	10 mT/m	10 mT/m	Unchanged
Gantry opening	160 x 340 mm	160 x 336 mm	
Magnetic system weight	900 Kg	1000 Kg	

**General**

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
Size	2 m2 footprint	2 m2 footprint	The modularity concept introduced with ARTOSCAN M allows a greater flexibility in siting. If desired by the user, also an ARTOSCAN system may be separated in modules so allowing the same flexibility than the "M" version.
RF shielding	Self contained RF shielding (up to 50 dB@V/m) * External shielding (up to 100 dBu V/m) (optional)	Self contained RF shielding (up to 80 dB $\mu$ V/m) * <i>Shielding cloth cover (up to 90 dBuV/m) (optional)</i> * External shielding (up to 110 dBuV/m) (optional)	A different technical solution has allowed to achieve better results in the standard configuration. A shielding cloth cover has been added as an intermediate solution between the standard configuration and an external shielding for those sites that are a little bit noisy than the usual ones. The same solution had been already adopted by HITACHI in the NW-5000 (510(k) accession number: K911642),
Patient positioning	Automatically, by the coil and a proper mechanical gantry structure. The coil is pushed into the gantry manually.	Automatically, by the coil and a proper mechanical gantry structure. The coil is pushed into the gantry manually,	Unchanged
Limb fastening	All coils are especially designed to fasten in a proper position the examined area. As for the knee, in particular, a special locking device is provided to fasten the foot and the leg to allow the control of both knee extension/flexion movements and intra- and extra-rotations.	All coils are especially designed to keep the examined limb in the proper position. <i>Special locking devices are provided for kinematic exams of leg and wrist (optional).</i>	A special device for the wrist has been added to study those pathologies that may benefit a kinematic examination (e.g. carpal instability). See for instance Resonex - Kinematic MRI moviemaker (K924154)

**General**

Characteristics	ARTOSCAN	ARTOSCAN M	Comments
Patient comfort	The patient is completely out of the magnet, except the examined portion, eliminating claustrophobia and other related reactions during the examination	The patient is completely out of the magnet, except the examined portion, eliminating claustrophobia and other related reactions during the examination	
<i>Network capability(optional)</i>	<i>Ethernet local network</i>	<i>* Ethernet thin wire local connection through DICOAF protocol</i> <i>* Ethernet thin wire local connection through TCP/IP protocol</i> <i>* Remote connection through modem</i>	With the present release, the DICOM protocol is available (at the moment DICOM is the most accredited communication standard) and both local and remote connections are provided.
<i>Additional console (optional)</i>	n.a.	<i>Includes all the image processing functions available on the main system. Configuration:</i> <i>CPU.- Pentium I 00 Mhz</i> <i>Main memory: 32 MR</i> <i>3-1/4 " Hard disk: 2 GB</i>	
Type of installation	Fixed site ("Permanently installed" according to IEC 601-1)	Fixed site ("Permanently installed" according to IEC 601-1) Mobile	<div style="border: 1px solid black; border-radius: 50%; padding: 10px; display: inline-block;">           ARTOSCAN and ARTOSCAN M may be installed also as mobile systems. See for instance HITACHI Mobile NW-7000 (K920159)         </div>