K060956

MAY 4 2006

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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Contact Person: Carri Graham

Date: April 4, 2006

807.92(a)(2)

Trade Name: E-Scan Opera

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

Esaote	E-Scan XQ	K032121
Siemens	Magnetom Vision	K945517
Esaote	G-Scan	K042236

807.92(a)(4)

Device Description

Summary of E-scan XQ modifications

The changes performed on the modified E-scan XQ device (E-scan Opera), with respect to the cleared version – E-scan XQ K032121 –, 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. A lower patient table.
2. A panel with a LCD screen on the front of the magnet.
3. Some different external covers due to the patient table lowering and for renewing the equipment aesthetics.
4. Upgrading of the electronics.
5. A new software release.

E-scan Opera

The system is composed of these main parts:
1. Patient positioning table.
2. Magnetic unit with the display panel.
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 Opera 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 Opera 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.

807.92(a)(6)

Technological Characteristics

The modifications to the E-scan XQ system, reflected in this Special 510(k), do not alter the fundamental scientific technology of the system.

Characteristic	E-scan Opera	E-scan XQ K032121	Comments
Patient table:	Maximum load-bearing capacity = 200 kg (approx. 440 lb) fixed height (710 cm) removable from magnet cavity to facilitate patient positioning one section of the bed can be rotated to enable various positions in relation to the region examined (right or left) washable covering material manual positioning integrated in overall design of equipment.	Maximum load-bearing capacity = 200 kg (approx. 440 lb) fixed height (910 cm) removable from magnet cavity to facilitate patient positioning one section of the bed can be rotated to enable various positions in relation to the region examined (right or left) washable covering material manual positioning integrated in overall design of equipment.	The patient table of the E-scan Opera is 20 cm lower than the unmodified E-scan XQ patient table to allow a more easy and comfortable patient positioning (see Device Modification Description section).

Characteristic	E-scan Opera	G-scan K042236	Comments
Magnetic unit display panel:	The function of the Display Panel is displaying real time sequences for patient positioning. Present commands: Preview: begins the real time sequence and displays the acquired image on the LCD panel in the selected orientation (sagittal, axial, coronal). Abort: stops the running sequence.	The function of the Control Panel is managing the movement of the magnet and of the patient table and displaying real time sequences for patient positioning. Besides the movement commands the following commands are also present: Preview: begins the real time sequence and displays the acquired image on the LCD panel in the selected orientation (sagittal, axial, coronal). Abort: stops the running sequence.	The E-scan Opera system, as the unmodified E-scan XQ, has no motorized movement. So the function of the Display Panel is only verifying the correct centering of the region being examined (see Device Modification Description section).

Characteristic	E-scan Opera	G-scan K042236	Comments
Electronics box and operating console:	The signals from the electronics box to the operating console pass through a fiber optic cable. The operating console is powered directly by the mains.	The signals from the electronics box to the operating console pass through a fiber optic cable. The operating console is powered directly by the mains.	See Device Modification Description section.
Electronics box:	ALDIM unit: supplies the Display Panel.	ALEL unit: supplies the Control Panel and the CCE unit, which drives the electric motor and activates the solenoid valves of the hydraulic circuit.	See Device Modification Description section.
SW version 9.2A:	Reconstruction process on Host instead of on DSP.	Reconstruction process on Host instead of on DSP.	See Software Description section.

Characteristic	E-scan Opera	MAGNETOM Vision K945517	Comments
SW version 9.2A:	RF saturation pulses are used to suppress flow and motion artifacts. Pre-saturation regions may be arbitrarily located in any orthogonal or oblique orientation.	RF saturation pulses are used to suppress flow and motion artifacts. Pre-saturation regions may be arbitrarily located in any orthogonal or oblique orientation.	See Software Description section.
	The Repetition Time (TR) of each sequence can be set using fixed step so that 50 or 60 Hz artifacts, caused by external magnetic fluctuation, can be avoided.	Physiologically controlled imaging: pseudogating is obtained with a TR corresponding to the RR interval in the cardiac cycle. This application is used to prevent flow artifacts (assuming a stable heart rate).	The same technique is used to avoid AC power line artifacts (E-scan Opera) and motion artifacts caused by heartbeat (MAGNETOM Vision). See Software Description section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 4 2006

Esaote, S.p.A.
% Ms. Carrie Graham
Consultant
Anson Group, LLC
11460 N Meridian St., Ste 150
CARMEL IN 46032

Re: K060956
Trade/Device Name: E-scan Opera
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 6, 2006
Received: April 7, 2006

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/industry/support/index.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): K060951

Device Name: E-scan Opera

Indications for Use:

E-scan Opera 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.

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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 A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060956