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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

Carri Graham, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Carri Graham

Date: April 30, 2004

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	E-Scan	K990968
Esaote	E-Scan	K001894
Esaote	Hip Coil	K012728
Esaote	E - Scan XQ	K020164
Esaote	E-Scan XQ	K032121

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807.92(a)(4)

Device Description

The DPA Shoulder Coil is to be used with the E-scan XQ magnetic resonance imaging system. It is a receiving coil designed to be "worn" by the patient and is the result of the combination of two different coils. The first is the primary coil and is composed of 4 turns connected in a series with 4 tuning capacitors positioned under the patient's armpit. The second surface coil consists of 3 turns designed to improve the image homogeneity and having spatially complementary sensitivity with respect to the primary coil. The coil allows for imaging of both the left and right shoulder, due to the symmetrical mechanical connection between its base and the magnet.

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 upper limb, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging the lower limb, 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.

807.92(a)(6)

Technological Characteristics

Comparison to the cleared device E-scan XQ K032121

Characteristics	E-scan XQ K032121	Modified E-scan XQ	Comments
DPA receiving coils	2 Knee coil: 22.5 x 21.0 x 18.3 cm (h x w x d) external; 14.3 x 16.0 x 18.3 cm (h x w x d) internal 3 Hand coil: 17.8 x 17.5 x 20 cm (h x w x d) external; 11.9 x 7.2 x 20 cm (h x w x d) internal 4 Foot/Ankle coil: 22.0 x 19.2 x 28.5 cm (h x w x d) external; 14.6 x 10.0 x 28.5 cm (h x w x d) internal	2 Knee coil: 22.5 x 21.0 x 18.3 cm (h x w x d) external; 14.3 x 16.0 x 18.3 cm (h x w x d) internal 3 Hand coil: 17.8 x 17.5 x 20 cm (h x w x d) external; 11.9 x 7.2 x 20 cm (h x w x d) internal 4 Foot/Ankle coil: 22.0 x 19.2 x 28.5 cm (h x w x d) external; 14.6 x 10.0 x 28.5 cm (h x w x d) internal 7 Shoulder coil: 25.5 x 18.5 cm (larger opening) 13.3 x 13.3 cm (smaller opening)	The technological characteristics of the DPA 7 Shoulder coil are similar to the characterisitics of the predicate device DPA receiving coils. The coil is designed to be morphologically adapted to the examined area for increasing the Signal-to-Noise Ratio. See section " DPA Shoulder Coil Description ".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2004

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

Re: K041145
Trade/Device Name: E-scan XQ MRI System
Regulatory Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: April 30, 2004
Received: May 3, 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): K041145

Device Name: E-scan XQ MR System

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 upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, and imaging portions of the lower limb, 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 __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. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041145