FEB 1 2 2002

K020164

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

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

Contact Person: Colleen Densmore

Date: January 4, 2002

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	Artoscan M	K963262
Esaote	E-Scan	K990968
Esaote	E-Scan	K001894
Esaote	Hip Coil	K012728

807.92(a)(5)

Intended Use(s)

The E-scan XP is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. 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.

807.92(a)(6)

Technological Characteristics

The E-Scan XP MRI system is substantially equivalent to the currently available E-Scan system cleared via K012728.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Esaote, S.P.A.
% Ms. Colleen J. Densmore
Official Correspondent
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K020164
Trade/Device Name: E-Scan XQ MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: January 4, 2002
Received: January 17, 2002

Dear Ms. Densmore:

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 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 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:

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" (21 CFR Part 807.97). 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): [redacted] K020164

Device Name: E-Scan XQ

Indications for Use:

The E-scan XQ is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. 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 _____

Norman C Baxton

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020164