K110238
P1/2

FEB 17 2011

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

Submitter Information

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Date: January 21, 2011

Trade Name: G-Scan

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

Predicate Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
G-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A	K042236
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K080968
O-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K092469

510(k) Summary
G-Scan
Esaote S.p.A.

Device Description

G-scan is a Magnetic Resonance (MR) system, which produces images of the internal structures of the patient's limbs and joints.

The changes performed on the modified G-scan device, with respect to the cleared version – G-scan K042236 –, are due to the improvement of the system safety and performance. These modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

1. A modified version of the magnet poles and of the gradient coils.
2. New receiving coils.
3. Modified pulse sequences.
4. A new Emergency button procedure.
5. A new safety device named sensitive edge.
6. A new safety switch named "Bed in"
7. A hand protection for patient table.
8. A head protection for patient table.
9. An exam positioning indicator kit for patient table.
10. A new step for patient positioning.
11. Contraindications have been added in the user manual due to the possibility of patient syncope caused by protracted orthostatic positions required for the examination.
12. A new software release.

Intended Use(s)

G-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

G-scan 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.

Technological Characteristics

The changes to the G-scan system, reflected in this Special 510(k), do not alter the fundamental scientific technology of the G-scan system, the predicate device, cleared via K042236.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Esaote S.p.A
c/o Ms. Allison Scott
Regulatory Associate
Anson Group, LLC
11460 N Meridian Street, Suite 150
CARMEL IN 46032

FEB 17 2011

Re: K110238
Trade Name: G-Scan
Regulation Number: 21 CFR § 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 21, 2011
Received: January 26, 2011

Dear Ms. Scott:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K110238

Indications for Use

510(k) Number (if known): K110238

Device Name: G-Scan MR System

Indications for Use:

G-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

G-scan 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)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110238