K052077

AUG 16 2005

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
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Contact Person: Carri Graham

Date: July 29, 2005

807.92(a)(2)

Trade Name: G-scan

Common Name: Coil, Magnetic Resonance Specialty

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90MOS

807.92(a)(3)

Predicate Device(s)

Esaote	G-scan	K042236

807.92(a)(4)

Device Description

The Cervical Spine Coil is to be used with the MRI system G-scan, cleared via K042236.

This is a solenoidal linear receiving coil, shaped for suitability to the areas under examination and designed to be matched to the patient's cervical vertebrae; the coil is also morphologically adapted to the examined area to obtain a good Signal-to-Noise Ratio.
The patient's neck is inserted into the coil after the coil itself has been opened by means of non-magnetic contacts inserted in the coil loops.
The height of the patient's head can be regulated by a suitable mechanism with a lever command.
A special cushion is attached to the coil assuring that the patient maintains comfortably his position during the examination.
The mechanical connection between the coil and the patient table is provided through a mechanism that positions the coil at the proper position for a cervical examination.
The coil is equipped with a connecting cable, which must be fitted to the connector on the patient table for proper electrical wiring and for automatic coil model recognition.
The coil resonator is composed of 3 copper tubes each one with two couples of non-magnetic contacts; the three tubes are arranged in a circular path and connected in series and with 3 tuning capacitors groups.
De-coupling between the transmitting and the receiving coil is accomplished via a couple of PIN diodes in a passive circuit. During the RF transmitting pulse, the diodes placed in the receiving coil decoupling circuit are switched on by the pulse and enable a LC parallel resonating circuit, at the working frequency, so that the overall impedance of the coil becomes very high and the parasitic current is minimised.

807.92(a)(5)

Intended Use(s)

The G-scan Cervical Spine Coil is to be used in MR imaging of the cervical section of the spine column.

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 portions of the spinal column, including the cervical, thoracic and lumbo-sacral sections.

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.

The indications for use of the G-scan MRI system with the Cervical Spine Coil are the same as those for the G-scan previously cleared via K 042236.

807.92(a)(6)

Technological Characteristics

The technological characteristics of the Cervical Spine Coil are similar to the characterisitics of the predicate device linear receiving coils.
The coil is designed to be morphologically adapted to the examined area for increasing the Signal-to-Noise Ratio.

Substantial Equivalence Comparison Table

Characteristics	G-scan K042236	Modified G-scan
Cervical Spine Coil	Linear Receiving Coils: - Shoulder coil 1: 22.4 x 21.6 x 12.6 cm (h x w x d) external; 14.5 x 17.5 x 12.6 cm (h x w x d) internal - Flexible coil 6: 4.0 x 33.0 x 28.5 cm (h x w x d) maximum external - Thoracic 8 – Lumbar Spine coil: 4.5 x 32.2 x 28.4 cm (h x w x d) maximum external DPA Receiving Coils: - Knee coil 2: 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 - Hand coil 3: 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 - Foot/Ankle coil 4: 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 - Shoulder coil 7: 21.5 x 30.0 x 21.8 cm (h x w x d) maximum external	Linear Receiving Coils: - Shoulder coil 1: 22.4 x 21.6 x 12.6 cm (h x w x d) external; 14.5 x 17.5 x 12.6 cm (h x w x d) internal - Flexible coil 6: 4.0 x 33.0 x 28.5 cm (h x w x d) maximum external - Thoracic 8 – Lumbar Spine coil: 4.5 x 32.2 x 28.4 cm (h x w x d) maximum external - Cervical Spine Coil 9: 26.4 x 32.1 x 36.6 cm (h x w x d) maximum external; 17.5 x 15.1 x 5.0 cm (h x w x d) internal DPA Receiving Coils: - Knee coil 2: 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 - Hand coil 3: 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 - Foot/Ankle coil 4: 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 - Shoulder coil 7: 21.5 x 30.0 x 21.8 cm (h x w x d) maximum external

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

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

Re: K052077
Trade/Device Name: G-scan Cervical Spine Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 29, 2005
Received: August 1, 2005

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): K052077

Device Name: G-scan Cervical Spine Coil

Indications for Use:

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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 portions of the spinal column, including the cervical, thoracic and lumbo-sacral sections.

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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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052077