



Food and Drug Administration
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Esaote S.p.A
% Allison Scott, RAC
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October 25, 2016

Re: K161973
Trade/Device Name: G-scan Brio, S-scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, MOS
Dated: September 23, 2016
Received: September 26, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light gray watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K161973

Device Name
G-scan Brio and S-scan

Indications for Use (Describe)

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the head, limbs, joints and spinal column. It is intended for imaging the head, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.

G-scan Brio 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 use of MR equipment, the images can provide diagnostically useful information.

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the head, limbs, joints and spinal column. It is intended for imaging the head, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.

S-scan Brio 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 use of MR equipment, the images can provide diagnostically useful information.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: September 20, 2016

Trade Name: G-scan Brio and S-scan

Classification Panel: Radiology

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: LNH, MOS

Predicate Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
G-scan Brio	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K142421
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K161238

Reference Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
IRIS II	System, nuclear magnetic resonance imaging	II	LNH	Hitachi Medical Systems America	K994378
MAGNETOM Concerto	System, nuclear magnetic resonance imaging	II	LNH	SIEMENS	K003192

Device Description

The change performed on the modified G-scan Brio, with respect to the cleared version – G-scan Brio K142421 – are due to the improvement of the system performance. This modification is for the introduction of the new Shoulder Coil 20 code 130000014 (already cleared with S-scan K161238), the Head Coil 16 code 13000100, and the head indication for use.

The change performed on the modified S-scan, with respect to the cleared version – S-scan K161238 – are due to the improvement of the system performance. This modification is the introduction of the new Head Coil 16 code 13000100 and the head indication for use.

Intended Use(s)

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the head, limbs, joints and spinal column. It is intended for imaging the head, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.

G-scan Brio 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 use of MR equipment, the images can provide diagnostically useful information.

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the head, limbs, joints and spinal column. It is intended for imaging the head, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.

S-scan Brio 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 use of MR equipment, the images can provide diagnostically useful information.

Technological Characteristics

The technological characteristics of the G-scan Brio and S-scan systems with the addition of the Shoulder Coil 20, Head Coil 16, and Head indication, reflected in this 510(k), do not alter the scientific technology of the G-scan Brio and S-scan systems and are substantially equivalent to those of the predicate devices.

The Shoulder Coil 20 has been designed in order to have bigger dimension (to allow an increased number of possible patient examinations and an extra receiving channel) and increased image quality than the 2Ch Shoulder Coil 7 (already cleared for the G-scan Brio and S-scan systems). The Head Coil 16 has been designed in order to allow head imaging.

The 3Ch Shoulder Coil and 2Ch Shoulder Coil have a similar shape, can be tilted on their base to allow left or right shoulder examination and both are embraced by the patient during examination.

Summary of Non-Clinical Tests

The G-scan Brio and S-scan have been evaluated to demonstrate substantial equivalence related to biocompatibility, medical electrical equipment, risk management, software verification and validation, and image quality and has been found to conform to the following medical device safety standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-2-33
- ISO 14971
- ISO 62304
- IEC 62366
- NEMA MS-1
- NEMA MS-3

Summary of Clinical Tests

Sample clinical images and attestation from a U.S. Board-Certified Diagnostic Radiologist that the images are of good diagnostic quality were provided as part of this submission.

Conclusion

The non-clinical testing demonstrates that the G-scan Brio and S-scan are as safe, as effective, and performs as well as or better than the predicate. G-scan Brio and S-scan are substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.