DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ESAOTE S.p.A.
% Ms. Allison Scott
Senior Regulatory Consultant
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

July 8, 2016

Re: K161238
Trade/Device Name: S-scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: June 8, 2016
Received: June 9, 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

~~UNKNOWN~~ K161238

Device Name

S-Scan

Indications for Use *(Describe)*

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.
S-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spinlattice 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Special 510(k) Summary

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

Submitter Information

Esaote S.p.A.
Via Siffredi 58
16153 Genova - Italy

Contact Person: Allison Scott, RAC
Senior Regulatory Consultant
Tel. 317.228.8719
Fax 317.228.8701
allison.scott@navigant.com

Date: June 9, 2016

Tradename: S-scan

Classification Name: Magnetic Resonance Diagnostic Device

Classification Panel: Radiology

Classification Number: 90LNH

Predicate Devices

Trade name	Common name	Class	Product code	Manufacturer	K number
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A	K153039

Device Description

The change performed on the modified S-scan, with respect to the cleared version, S-scan K153039, is due to the improvement of the system performance. This modification, which does not affect the intended use or alter the fundamental scientific technology of the device, is the introduction of the Shoulder Coil 20 code 130000014. The Shoulder Coil N.20 is a three channels receiving coil. Its intended use is for shoulder examination on the S-scan. The Shoulder Coil is a wearable rigid coil equipped with an adaptor for fast placement in the patient table. The same adaptor matches for patient laterality *(left /right shoulder)*.

Intended Use

S-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal, 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, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.
S-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spinlattice 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 S-scan systems with the addition of the Shoulder Coil 20 option, reflected in this Special 510(k), do not alter the scientific technology of the S-scan system 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 S-scan system).

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 devices have been evaluated for biocompatibility, electrical, electromagnetic, and mechanical safety, and have 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
- IEC62304
- IEC62366
- ISO10993-1
- ISO 14971-2
- NEMA MS-1 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS-3 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images

Summary of Clinical Tests

No clinical tests were performed.

Conclusion

The changes proposed to the S-scan System are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.