Esaote S.p.A
% Allison Scott, RAC
Associate Director
Navigant Consulting, Inc
9100 Keystone Crossing, Suite 500
INDIANAPOLIS IN 46240

January 22, 2019

Re: K183685
Trade/Device Name: O-Scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: December 27, 2018
Received: December 28, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183685

Device Name
O-Scan

Indications for Use *(Describe)*
O-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal, coronal and oblique section images of limbs and joints. It is designed for imaging portions of the arm, including hand, wrist, forearm, and elbow, but excluding the upper part of the arm and portions of the leg, including foot, ankle, calf, and knee, but excluding the thigh.
The M.R. images produced by O-scan correspond to the spatial distribution of the
protons (hydrogen nuclei) which verify the properties of magnetic resonance and depend on the MR parameters spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nucleus 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

Esaote, S.p.A.
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Contact Person: Allison Scott, RAC
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Date: December 21, 2018

Trade Name: O-scan

Classification Panel: Radiology

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

Predicate Device(s)

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

Reference Device(s)

ACHIEVA 1.0T	System, nuclear magnetic resonance Imaging	II	LNH	PHILIPS MEDICAL SYSTEMS	K052078
G-scan Brio	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K180592

510(k) Summary
O-scan
Esaote S.p.A.

Device Description

The changes performed on the modified O-scan, with respect to the cleared version – O-scan K092469 are due to the upgrade of the software system. These modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- A new Software version (EVO'18) including the following features:
    1. AGilExam (automatic slice positioning for the examination of the anatomical regions of knee, ankle and wrist)
    2. 3D Viewer; this is an option that - starting from the acquired data cube - allows the running of a 3D viewer in which to reconstruct the desired 3D series, both using the three projections of the acquired package and generating a special MPR curve as reference. (Previously cleared by FDA via K180592 on G-Scan Brio)

Intended Use(s)

O-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal, coronal and oblique section images of limbs and joints. It is designed for imaging portions of the arm, including hand, wrist, forearm, and elbow, but excluding the upper part of the arm and portions of the leg, including foot, ankle, calf, and knee, but excluding the thigh. The M.R. images produced by O-scan correspond to the spatial distribution of the protons (hydrogen nuclei) which verify the properties of magnetic resonance and depend on the MR parameters spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nucleus 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 O-scan systems with the addition of AgilExam and 3D Viewer, reflected in this 510(k), do not alter the scientific technology of the O-Scan systems and are substantially equivalent to those of the predicate devices. The modification are implemented in order to improve display, analysis and comparison of Magnetic Resonance images.

Summary of Non-Clinical Tests

The O-Scan has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, and software verification and validation 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

No clinical tests are included within this submission.

Conclusion

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