Esaote S.p.A.
%Alberto Carcagni
Regulatory Affairs Officer
Via Enrico Melen 77
Genoa, Genoa 16152
ITALY

February 4, 2022

Re: K212419
Trade/Device Name: Magnifico Open, Magnifico MSK
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: July 26, 2021
Received: January 5, 2022

Dear Alberto Carcagni:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212419

Device Name
Magnifico (Magnifico Open and Magnifico MSK configurations)

Indications for Use *(Describe)*

The general-purpose magnetic resonance imaging (MRI) system is designed to scan any targeted area of the body, to collect, display and analyse MR images and other real-time imaging procedures.
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, the lumbar and the sacral sections as portions of the spinal column, imaging the pelvis and imaging the head.
Outcomes related to diagnosis:
Magnifico is a Magnetic Resonance (MR) system that produces cross-section images of the limbs, joints, spinal column, pelvis and head. MRI provides better soft tissue contrast than CT and can differentiate better between fat, water, muscle, and other soft tissue than CT (CT is usually better at imaging bones). These images provide information to physicians and can be useful in diagnosing a wide variety of diseases and conditions.

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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K212419

6 - 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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Date: July 2021

Trade Name: Magnifico

Classification Panel: Radiology

Classification Name(s): Magnetic Resonance Diagnostic Device

Product Code: LNH

Predicate Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K161973
G-scan Brio	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K180592

Device Description

Magnifico is a Magnetic Resonance (MR) system with two configurations:

1. Magnifico Open, "Whole body" configuration (all above listed, in intended use, anatomical regions)
2. Magnifico MSK, musculoskeletal configuration (all above listed anatomical regions, excluded head and pelvis)

which produces images of the internal structures of the patient's limbs, joints and spinal column.
The system comprises four main parts:

- Patient Table
- Magnetic Unit, containing a permanent magnet
- Console, comprising a PC, keyboard, mouse, monitor and operating table
- Electronic box

Magnifico has an open magnet that makes comfortable MRI exam for all patients, including claustrophobic patients, in particular children.
Additionally, Magnifico comes with a transparent headcoil for enhanced patient comfort.

Magnifico is similar to Esaote S-scan system, cleared via K161973
With respect to the predicate devices, Magnifico introduces improvements, a new software release and few features.
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'21) including the following features:
    1. Pelvis anatomical district
    2. Hip scan Bilateral (instead of unilateral as for Esaote S-scan and G-scan Brio)
- A new multi-channel technology C-spine coil for cervical application and a new coil for knee scan
- 0.4T Magnet instead of the 0.25T installed in S-scan.

Indications for Use

The general-purpose magnetic resonance imaging (MRI) system is designed to scan any targeted area of the body, to collect, display and analyse MR images and other real-time imaging procedures. 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, the lumbar and the sacral sections as portions of the spinal column, imaging the pelvis and imaging the head.
Outcomes related to diagnosis
Magnifico is a Magnetic Resonance (MR) system that produces cross-section images of the limbs, joints, spinal column, pelvis and head. MRI provides better soft tissue contrast than CT and can differentiate better between fat, water, muscle, and other soft tissue than CT (CT is usually better at imaging bones). These images provide information to physicians and can be useful in diagnosing a wide variety of diseases and conditions.

The technological characteristics of the Magnifico systems with the addition of new 0.4T Magnet**, Pelvis anatomical district and Bilateral Hip scan, reflected in this 510(k), do not alter the scientific technology of the Magnifico systems and are substantially equivalent to those of the predicate devices. The modification are implemented in order to improve image quality, analysis and comparison of Magnetic Resonance images.

**The new magnet is always a permanent one, based on NdFeB (neodymium), C-shape, with the bed positioned across the magnet and orthogonally to it, as for the previous 0.25T Magnet.

Summary of Non-Clinical Tests

The Magnifico 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

Within this submission is included a complete set of clinical images in DICOM format, for all anatomical regions foreseen in the intended use with the sequences commonly used for these anatomies. The clinical images were acquired and found to be of good diagnostic quality by the board-certified radiologist, Dr. Mark Awh, diplomat American Board of Radiology and president of RadSource.

Conclusion

The Non-clinical testing demonstrates that the Magnifico is safe. Clinical Testing, with clinical images quality, comparable to those obtained from similar MRI equipment, demonstrate that Magnifico is effective and performs as well as or better than the predicate system. Magnifico is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.