March 5, 2026

Esaote, S.P.A.
Antonia Perrella
Regulatory Affairs Leader
Via Enrico Melen, 77
Genoa, GE 16152
Italy

Re: K251901
Trade/Device Name: Magnifico Open (100009900)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: February 4, 2026
Received: February 4, 2026

Dear Antonia Perrella:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251901

Please provide the device trade name(s).

Magnifico Open (100009900)

Please provide your Indications for Use below.

The general-purpose magnetic resonance imaging (MRI) device is designed to scan any targeted area of the body, to collect, display and analyse MR images and other real-time imaging procedures.
The indications for use are the following:
Imaging portions of calf, knee, ankle, foot, thigh, hand, wrist, forearm, elbow, arm, shoulder, hip, lumbar column, sacral column, cervical column, thoracic spine, pelvis, temporomandibular joint (included only for "Open" configuration), head (included only for "Open" configuration) and upper abdomen (included only for "Open" configuration under option).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251901

510(k) Summary

Prepared on: 2026-02-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Esaote S.p.A.
Applicant Address	via Enrico Melen 77 Genoa GE 16152 Italy
Applicant Contact Telephone	+39 380 2346712
Applicant Contact	Ms. Antonia Perrella
Applicant Contact Email	fda@esaote.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Magnifico Open (100009900)
Common Name	Magnetic resonance diagnostic device
Classification Name	System, Nuclear Magnetic Resonance Imaging
Regulation Number	892.1000
Product Code(s)	LNH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
k241133	Magnifico Open	LNH

Device Description Summary

21 CFR 807.92(a)(4)

Magnifico device is a Magnetic Resonance (MR) system that produces cross-section images of the internal structures of the body. 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.
The updated Magnifico is the evolution of its predicate device, the Magnifico device cleared via K241133. Compared to the predicate device, the following modifications have been introduced:
- A new software version (MRI EVOlution 25), including:
  > The optional functionality "HyperClarity", an AI-based algorithm for MRI image enhancement (K230854), integrated without any modification. The algorithm is classified under a different regulation in its 510(K) and this is out-of-scope from the current submission of the subject device.
  > Abdominal Imaging package for abdomen examination, which delivers:
    - Patient's breathing management (including respiratory movement reduction techniques)
    - ROTAR sequences
    - 3D FSE sequences
- Introduction of a patient breathing detection device (Respiratory Gating System)
- Introduction of a support for spontaneous movements of the knee (flexion/extension)
- A modification of the maximum gradient intensity
- New receiving Coils: DPA Shoulder Coil, Flex Coil, 4 ch. Foot/Ankle coil

Magnifico is substantially equivalent to the predicate device with respect to the fundamental scientific technology, technological characteristics and the principle of operation. The core components remain unchanged and are identical to those of the cleared Magnifico device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The general-purpose magnetic resonance imaging (MRI) device is designed to scan any targeted area of the body, to collect, display and analyse MR images and other real-time imaging procedures.
The indications for use are the following:
Imaging portions of calf, knee, ankle, foot, thigh, hand, wrist, forearm, elbow, arm, shoulder, hip, lumbar column, sacral column, cervical column, thoracic spine, pelvis, temporomandibular joint (included only for "Open" configuration), head (included only for "Open" configuration) and upper abdomen (included only for "Open" configuration under option).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The new version of the Magnifico device introduces the imaging of the upper abdomen among the indications for use. The intended use remains unchanged: "The general-purpose magnetic resonance imaging (MRI) device is designed to scan any targeted area of the body, to collect, display and analyse MR images and other real-time imaging procedures".

Technological Comparison

21 CFR 807.92(a)(6)

The updated Magnifico is substantially equivalent to the predicate device cleared via K241133, with regard to the technological characteristics, safety and effectiveness.
No modifications have been made to the magnet design, the core components remain unchanged and are identical to those of the primary predicate device.
The updated Magnifico employs the same fundamental scientific technology as the predicate device.
Magnifico and its predicate device are intended for general-purpose magnetic resonance imaging (MRI).
Magnifico and its predicate device have the same application environment and intended users.
Magnifico and its predicate device have the same magnetic system and filed strength.
The new version of the Magnifico device introduces improvements, a new software release and few features. Specifically:
- HyperClarity, an AI-based algorithm for MRI image enhancement (K230854), integrated without any modification. The algorithm is classified under a different regulation in its 510(k) and this is out-of-scope from the current submission of the subject device.
- Abdominal imaging, supported by the use of coils already available on the predicate device. The abdominal Imaging package provides the following features:
  > patient breathing management, including the respiratory movement reduction through the "Breath-hold", "Gating", "Breath Sync" and "Trigger" acquisition techniques.
  > 3D FSE sequences, a 3D extension of the FSE sequences already available on the cleared Magnifico device.
  > ROTAR sequences, a variant of the cleared FSE method, which exploits the well-established PROPELLER reconstruction method.
The abdominal imaging is already implemented in the reference device (K233629).
- Modification of the maximum gradient intensity, not altering the design or the fundamental operating principle of the device.
- Patient breathing detection device, to detect the patient's breathing, used for the execution of the "Breath-hold", "Gating", "Breath Sync" and "Trigger" acquisition techniques.
- Support for spontaneous movements of the knee, to improve the image workflow of the knee at different degrees of flexion/extension.
- New coils:
  > Flex coil, equivalent to the already cleared Esaote Hip coil;
  > DPA Shoulder coil, equivalent to the already cleared Esaote DPA Shoulder;
  > 4 ch. Foot/Ankle coil, equivalent to the already cleared Esaote Foot-Ankle coil.
All the new features can be considered consolidated MRI functions and represent an improvement over the cleared Magnifico device.
All necessary performance tests have been performed and the results show that the updated Magnifico meets its intended use and does not raise new questions of safety or effectiveness compared to the predicate device.

Reference Devices:
In addition to the predicate device (K241133), two legally marketed devices were used as reference devices to support specific technological aspects of the subject device:
– APERTO Lucent MRI System (K233629), referenced for abdominal imaging functionalities;
– SwiftMR (K230854), referenced for the integration of HyperClarity, integrated without modification.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The Magnifico device has been evaluated for biocompatibility, cleaning and disinfection effectiveness, and thermal, electrical, electromagnetic, mechanical safety, and was found to comply with applicable medical device safety standards.
Magnifico has been evaluated and found to comply with the following applicable standards:
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-33
- IEC 62304

- IEC 60601-1-6
- IEC 62366-1
- ISO 10993-1
- ISO 14971
- NEMA MS-1
- NEMA MS-3
- NEMA MS-14

Verification documents, validation documents, and test reports have been provided in this submission.
No new questions of safety and effectiveness were raised during non-clinical testing.

Sample clinical images acquired using the proposed updated device and reviewed by a U.S. board-certified radiologist have been included to demonstrate acceptable diagnostic image quality in accordance the FDA Guidance "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices".

A comparative evaluation of conventional images and images acquired using the Respiratory Gating System has been performed to demonstrate the clinical benefit of the patient breathing detection device in reducing respiratory motion artifacts.

Additional validation has been conducted for the HyperClarity feature. Specifically, performance testing and a validation based on radiologists' expert opinion have been conducted in order to demonstrate that HyperClarity performs as intended with the Magnifico device and the diagnostic quality of the images is maintained at the 0.4 T field strength.

The proposed device did not require clinical investigations to support substantial equivalence.

While there are some differences in technical features compared to the predicate device, the differences have been tested and the conclusions from all verification and validation data confirm that Magnifico meets all applicable safety and performance standards. Therefore, Esaote considers the subject device to be as safe, as effective, and with performance that is substantially equivalent to the predicate device.