



June 26, 2024

Esaote S.p.A.
Alberto Carcagnì
Regulatory Affairs Specialist
Via Melen 77
Genova, 16152
Italy

Re: K241133

Trade/Device Name: Magnifico Open (100009900); Magnifico MSK (100009910)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: June 6, 2024
Received: June 6, 2024

Dear Alberto Carcagnì:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue watermark of the letters 'FDA'.

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

510(k) Number (if known)
K241133

Device Name

Magnifico Open (100009900);
Magnifico MSK (100009910)

Indications for Use (Describe)

The general-purpose magnetic resonance imaging (MRI) device is designed to scan any targeted area of the body, to collect, display and analyze MR images and other real-time imaging procedures.

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).

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

| | |
|-----------------------------|---------------------------------|
| Applicant Name | Esaote S.p.A. |
| Applicant Address | Via Melen 77 Genova 16152 Italy |
| Applicant Contact Telephone | +39 338 7170634 |
| Applicant Contact | Mr. Alberto Carcagni |
| Applicant Contact Email | alberto.carcagni@esaote.com |

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

| | |
|---------------------|---|
| Device Trade Name | Magnifico Open (100009900); Magnifico MSK (100009910) |
| 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 |
|-------------|--|--------------|
| K212419 | Magnifico Open, Magnifico MSK | LNH |
| K032232 | Hitachi Airis Elite | LNH |
| K153736 | 3Mensio WORKSTATION | LLZ |

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The new Magnifico EVO 23 employs the same fundamental scientific technology as its predicate device, the first version of Esaote Magnifico, cleared via K212419.

The modifications, do not affect the intended use or alter the fundamental scientific technology of the device.

The software, used on the proposed Magnifico system has been modified, from EVO 21 to EVO 23, to include the

- LSDWI sequence for brain examination
- MR Angiography
- Maximum Intensity Projection (MIP)

and to support:

- Additional multi-channel technology coil for body
- Enhancement of PC board with new processor

Magnifico keeps all the other technological characteristics of the first cleared, version, as the 0.4T permanent Magnet, based on NdFeB (neodymium), C-shape.

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 analyze MR images and other real-time imaging procedures.
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).

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the new version of Esaote Magnifico MRI system are the same of the first version of Magnifico, registered via K212419.
Only the Outcome related to diagnosis, due to the introduction of a sub configuration of Magnifico (Magnifico MSK), contains, for new Magnifico EVO23, a distinguish of the configurations. This is irrelevant because the dossier is referred to the more complete Version of Magnifico

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technological characteristics of this device are similar to the primary predicate device. There has been no change to the magnet design or control system. The base elements of the operating system software are identical to the primary predicate device but the software have been improved with new functions like MR Angiography and DWI. Both are consolidated standard MRI functions, cleared also with a low field MRI as Hitachi Airis Elite.
The MIP feature is exactly the same that was firstly realized by 3Mension (in Esaote Group) for a S.a.M.D. called Warkstation and, successively, included in a Esaote software tool, called 3D Viewer registered, with G-scan Brio. Both S.a.M.D., Workstation and 3D viewer, have been FDA cleared, respectively via K153736 and K180592.
The additional body coil has the same technical characteristics of the coils cleared with Primary Predicate device Magnifico.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Software verification and validation activities are provided. Bench testing included assessing outputs from new features (LSDWI, MRA and MIP), image quality test, relevant electrical safety and electromagnetic compatibility tests. Surface heating testing and all relevant performance tests for the Body coil were provided. Sample clinical images for the new features were reviewed by a ACR registered radiologist and determined to be of good diagnostic quality. The testing and software documentation demonstrate that the Magnifico MRI system with EVO 23 Software release is substantially equivalent to the predicate device, and conform to applicable medical device safety and performance requirements.