



March 27, 2026

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

Re: K260746
Trade/Device Name: S-scan Open (100001800)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: March 6, 2026
Received: March 6, 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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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 faint, light blue background watermark of the FDA logo.

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.

K260746

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Please provide the device trade name(s).

?

S-scan Open (100001800)

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 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, hip, imaging the temporomandibular joint, imaging the cervical, the thoracic, the lumbar and the sacral sections as portions of the spinal column, and imaging the head.

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](#))

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Contact Details

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

Applicant Name	Esaote S.p.A.
Applicant Address	via Enrico Melen 77 Genoa 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	S-scan Open (100001800)
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
K161973	S-scan	LNH

Device Description Summary

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

'The S-scan Open 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.

S-scan Open represents the evolution of its predicate device, the Esaote S-scan, cleared under K161973 (initial clearance K063207). Compared to the predicate device, the following modifications have been introduced:

- Changes to the external design and shape, and an update of the electronics.
- Integration of the new software version MRI EVOLution 25, which provides compatibility with updated electronics, improvements in cybersecurity management, bug fixing and optimization, and includes the following features: management of new coils, 3D viewer, prone patient positioning management, SPED sequence, updated operating system, new graphical user interface, flow compensation feature extension, operator-selectable gradients direction, DWI (Diffusion Weighted Imaging) sequence, 2D SST1 sequence, and HyperClarity. Note: the subject device integrates the AI-based algorithm HyperClarity (SwiftMR, K230854) 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.
- Introduction of a patient alert system.
- Addition of new receiving Coils: XL flex L-Spine coil 10, Flex Coil 11, Knee Coil 21.

S-scan Open is substantially equivalent to the predicate device with respect to intended use, technical specifications, fundamental scientific technology and principle of operation.

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 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, hip, imaging the temporomandibular joint, imaging the cervical, the thoracic, the lumbar and the sacral sections as portions of the spinal column, and imaging the head.

Indications for Use Comparison

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

The indications for use of the S-scan Open device are identical to those of the S-scan previously cleared (K161973).

Technological Comparison

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

S-scan Open is substantially equivalent to the S-scan already cleared (K161973), with regard to the technological characteristics, safety and effectiveness.

The intended use of the S-scan Open remains unchanged from the predicate device.

S-scan Open and its predicate device have the same application environment and intended users.

S-scan Open employs the same fundamental scientific technology as the predicate device.

Core technical specifications, including the magnet characteristics and the filed strength, remain unchanged from the predicate device.

There are some differences summarized below.

Integration of the new software version MRI EVOLution 25 (F130001), which provides compatibility with updated electronics, improvements in cybersecurity management, bug fixing and optimization, and includes the following features:

- HyperClarity, an AI-based algorithm (SwiftMR, K230854) integrated without any modification; note: 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.

- 3D Viewer, already cleared with G-scan Brio (K180592).

- Prone Patient Positioning option already available on the cleared Magnifico (K251901).

- SPED (Spin-Echo with Dixon reconstruction technique) sequence: included in the "Spin Echo Fat & Water Separation" option, already available on the cleared Magnifico (K251901).

- New Operating System Windows 10, already implemented on the cleared Magnifico (K251901).

- New Graphic User Interface, already available on the cleared Magnifico (K251901).

- Flow compensation, already available on S-scan (K161973) and extended to all FSE family sequences.

- Operator-selectable direction of imaging gradients, already available on the cleared Magnifico (K251901).

- DWI LS acquisition, already available on the cleared Magnifico (K251901).

- 2D SST1 sequence (Gradient Echo "steady state" sequence).

The software modifications consist of features previously cleared on Esaote MRI systems and incremental enhancements to existing capabilities. These changes do not modify the intended use or the fundamental scientific technology.

New items listed below:

- Patient Alert System, providing the patient with a means to alert the operator if needed.

- New coils:

> XL flex L-Spine Coil is the same Esaote XL flex L-Spine Coil already cleared with the G-scan Brio (K142421).

> Knee coil 21 is the same Esaote Knee coil already available on the cleared Magnifico device (K251901).

> Flex coil is equivalent to the Esaote Hip coil n. 6 already cleared (K080968 and K042236).

All necessary performance tests have been performed to ensure the safety of the subject device. Verification and validation activities results demonstrate that the S-scan Open device meets its intended use, meets all applicable safety and performance standards and does not raise new questions of safety or effectiveness, compared to the predicate device.

Reference devices:

In addition to the predicate device (K161973), three legally marketed devices were used as reference devices to support specific technological aspects:

- G-scan Brio (K180592)

- Magnifico Open (K251901)

- SwiftMR (K230854)

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

Summary of Non-Clinical Tests:

The S-scan Open device has been evaluated and found to comply with the applicable requirements of the following 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-14

Verification and validation documents 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".

Summary of Clinical Tests:

The subject of this premarket submission did not require clinical investigations to support substantial equivalence.

Conclusion:

Although some differences in technical features exist compared to the predicate device, these differences have been evaluated through appropriate verification and validation activities, and the testing results confirmed that all predefined acceptance criteria were successfully met. Therefore, Esaote considers the subject device to be as safe, as effective, and with performance that is substantially equivalent to the predicate device.