July 31, 2026

Esaote, S.p.A.
Vanessa Ronconi
Regulatory Affairs Leader
Via Enrico Melen, 77
Genoa, GE 16152
Italy

Re: K261331
Trade/Device Name: I-Genius (100019400)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: July 2, 2026
Received: July 2, 2026

Dear Vanessa Ronconi:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

NINGZHI LI -S

Digitally signed by NINGZHI LI -S

For
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. | K261331 |

Please provide the device trade name(s).

I-Genius (100019400)

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 head. Target district: skull and brain.
The I-Genius device is intended to be used intraoperatively in a shielded operating room.

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |
| Please select the age group(s) for which the device(s) is to be used. | ☐ Neonates/Newborns (Birth to < 29 days old)<br>☐ Infants (29 days old to < 2 years old)<br>☐ Children (2 years old to < 12 years old)<br>☒ Adolescents (12 years old to < 22 years old)<br>☒ Adults (22 years old and greater) |

510(k) #: K261331

# 510(k) Summary

Prepared on: 2026-06-29

## 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 | +39 334 3432808 |
| Applicant Contact | Ms. Vanessa Ronconi |
| Applicant Contact Email | fda@esaote.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | I-Genius (100019400) |
| 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 |
|---|---|---|
| K260746 | S-scan Open | LNH |

## Device Description Summary

21 CFR 807.92(a)(4)

I-Genius is a Magnetic Resonance (MR) system that produces cross-section images of the head. 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.

I-Genius represents the evolution of its predicate device, the Esaote S-scan Open, cleared under K260746. Compared to the predicate device, the following modifications have been introduced:
- Introduction of the intraoperative system configuration
- New surgical bed
- New receiving coils: Head Coil, Human Large Head Coil, Flex Coil

I-Genius is substantially equivalent to the predicate device with regard to intended use, 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 head. Target district: skull and brain.
The I-Genius device is intended to be used intraoperatively in a shielded operating room.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The I-Genius indications for use do not introduce a new intended use compared to the predicate device. 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)

I-Genius is substantially equivalent to Esaote S-scan Open cleared under K260746 with regard to technological characteristics, safety, and effectiveness.
The intended use of the I-Genius device is the same as that of the predicate device.
I-Genius employs the same fundamental scientific technology as the predicate device.
I-Genius and the predicate device include the same magnetic unit. Core technical characteristics, including field strength, remain unchanged.
The software version remains unchanged from that previously cleared with the predicate device. All software functions available on I-Genius are already included in the cleared predicate device and are implemented without modifications.
There are some differences summarized below.

Compared to the predicate device, the following modifications have been introduced:
- Introduction of the intraoperative system configuration: the intraoperative deployment of MRI has already been implemented in other legally marketed MRI devices, such as the Altaire MR Interventional Package (K053309).
- New surgical bed, introduced to support the intraoperative system configuration and incorporating positioning functionalities and design solutions commonly adopted in surgical tables adapted for use in the MR environment.
- New receiving coils: Head, Human Large Head and Flex coils. The Head and Human Large Head coils are substantially equivalent to the Head coil 16 already available for use with the predicate device. The Flex coil is substantially equivalent to the Flex coil 11 already available for use with the predicate device.

These differences do not alter the intended use or the fundamental scientific technology of the device and do not raise new questions of safety or effectiveness compared to the predicate device.

In addition to the predicate device, the Altaire MR Interventional Package (K053309) was used as reference device to support specific technological aspects related to the intraoperative configuration.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Summary of Non-Clinical Tests:
The I-Genius device has been evaluated and found to comply with the applicable requirements of the following standards:
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-2-33
- IEC 60601-2-46
- IEC 62304
- IEC 62366-1
- ISO 10993-1
- ISO 14971
- NEMA MS-14

Verification and validation documents have been provided.
No new questions of safety and effectiveness were raised during non-clinical testing.

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

Summary of Clinical Tests:
The proposed device did not require clinical investigations to support substantial equivalence.

Conclusions:
Although some differences exist compared to the predicate device, these differences have been evaluated through appropriate verification and validation activities, and the testing results confirmed that I-Genius 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 that of the predicate device.