November 26, 2024

ASG Superconductors S.P.A.
% Silvia Tamarri
QA/RA Consultant
Thema S.r.l.
Via Giuseppe Saragat, 5
Imola, BO 40026
Italy

Re: K242258
Trade/Device Name: MROpen Evo (03-2000-00); MROpen Evo (03-4000-00)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: September 3, 2024
Received: September 3, 2024

Dear Silvia Tamarri:

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.

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242258

Device Name

MROpen Evo (03-2000-00);
MROpen Evo (03-4000-00)

Indications for Use *(Describe)*

Whole body magnetic resonance diagnostic medical device intended for the production of images for diagnostic purposes with transverse, coronal, sagittal and oblique orientation relating to the internal structures of the examined body areas, also including the examination of the brain through the DWI sequence, with limitations regarding cardiac, breast, lung and upper abdominal imaging.

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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510(k) #: K242258

510(k) Summary

Prepared on: 2024-10-04

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MROpen Evo (03-2000-00); MROpen Evo (03-4000-00)
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
K193116	MROpen EVO	LNH

Device Description Summary

21 CFR 807.92(a)(4)

MROpen Evo is a whole body magnetic resonance diagnostic medical device that acquires high-resolution medical images of various parts of the body. In particular, it produces images of the entire body except: upper abdomen, heart, lungs and breasts with transverse, coronal, sagittal and oblique orientation relating to the internal structures of the examined body areas, also including the examination of the brain through the DWI sequence.

The standard composition of the MROpen Evo device is:

- Magnetic Unit
- Operator PC
- Electronic Cabinet
- Penetration Filters
- Major Software MR GUI-PRO 3.1.

- Coil set (Body MAX, Head MAX, Hand MAX, Cervical MAX, Knee MAX, Multipurpose Linear, Flat Flex, Spine, Head-Neck, Long Spine, Shoulder)
- Cushions' Set

The device consists of two models, 03-2000-00 and 03-4000-00. The 03-4000-00 model of the MROpen Evo device has a very similar composition to the 03-2000-00 model, but most of the subassemblies that constitute it are replaced with others of equal functionality, in order to reduce production costs.
The MROpen Evo device allows the execution of standing imaging for those cases that require this need or facilitates acquisitions on patients suffering from movement disorders or suffering from claustrophobia. It is also possible to undergo this investigation in patients who have a high weight, but in any case, not exceeding 200 kg.
The software called MR GUI-PRO represents the set of SW modules necessary for the operation of the MROpen Evo MRI scanner based on the I-box spectrometer. The main modules act as a graphic interface for the operator and manage the execution of the exam. The MR GUI-PRO software has external interface elements, on the one hand the operator who interacts via monitor, keyboard and mouse and the other HW modules of the system and mainly: Gradient Amplifier, RF Amplifier, RF reception signal amplifier.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Whole body magnetic resonance diagnostic medical device intended for the production of images for diagnostic purposes with transverse, coronal, sagittal and oblique orientation relating to the internal structures of the examined body areas, also including the examination of the brain through the DWI sequence, with limitations regarding cardiac, breast, lung and upper abdominal imaging.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Predicate Device MROpen EVO (K193116) is a diagnostic total body imaging device with the following limitations: no cardiac imaging, no breast imaging.
The subject device MROpen Evo is developed for same applications. As the Predicate Device, it is a whole body magnetic resonance diagnostic medical device intended for the production of images for diagnostic purposes with transverse, coronal, sagittal and oblique orientation relating to the internal structures of the examined body areas. The subject device also has limitations in lung imaging and upper abdomen imaging, but this leds to a narrower scope of application compared to indications for use of the Predicate Device.
In every cases, MROpen Evo indications for use fall within the indications for use of the Predicate Device and the performances, the intended use and also the reference users are substantially equivalent.

Technological Comparison

21 CFR 807.92(a)(6)

The main change involving the technical and performance characteristics of the MROpen Evo device compared to the Predicate Device concerns the acquisition and reconstruction of images.
I-box 07 spectrometer, with a separate server, and Leybold 5000i cryocooler were introduced in the subject device and the new acquisition/reconstruction algorithm, named Compressed Sensing, was used to speed up MRI acquisition by acquiring less data through subsampling of k-space.

The I-box 01-1800-06 spectrometer of the Predicate Device integrated two logical components within a single enclosure: the reconstruction PC and the spectrometer boards. The proposed device contains only the spectrometer boards, with the PC board being replaced by an off-the-shelf server PC.
The two configurations are considered equivalent in terms of performance. The substantial equivalence is demonstrated by testing, with a Medical checklist (MedicalCheckList_3.1.0), different acquisitions, with all sequences interested by the change, that cover a large amount of the space of parameters that can be implemented. The checklist is repeated three times: with I-box 06, I-box 07 with Compressed Sensing and I-box 07 without Compressed Sensing.

For the MROpen Evo device, the Leybold 5000i cryocooler was introduced in addition to the models already available and used by the Predicate Device:
- 6000 H MD (compressor) + 10 MD (Cold Head) supplied by Leybold GmbH;
- F70 (compressor) + CH210L (Cold Gead) supplied by Sumitomo GmbH.

The cryocooler is a service component of the magnetic resonance system designed to cool the superconducting cable at cryogenic temperatures and does not affect the performance of the medical device. Functionality and performance remain equivalent in all three options and safety has been proven through dedicated tests carried out in accordance with IEC 60601-1.

Then, the reconstruction algorithm, named Compressed Sensing (CS), was introduced in the subject device to speed up MRI acquisition by acquiring less data through subsampling of k-space.
The tests carried out to compare the software performances of MROpen Evo with the Predicate Device showed that the introduction of CS software module leads to limited reconstruction errors and does not introduce artefacts in image processing compared to standard processing that does not use this reconstruction algorithm, as shown in the software test reports carried out in accordance with IEC 62304. So, the predicate and MROpen Evo performances are substantially equivalent.

The substantial equivalence between the legally marketed Predicate Device MROpen EVO (K193116) and the proposed device MRopen Evo is demonstrated by testing with a Medical checklist (MedicalCheckList_3.1.0).
The Medical Checklist consists in a list of acquisitions, with all sequences interested by the change to be tested, that cover a large amount of the space of parameters that can be implemented, with particular focus on the test of the behavior when the acquisition parameters are set to their boundaries, such as maximum number of slices, maximum and minimum TE and minimum voxel.
The pass criteria are the absence of unexpected artifacts.
The medical checklist (MedicalCheckList_3.1.0) is repeated three times: with I-box 06, I-box 07 with Compressed Sensing and I-box 07 without Compressed Sensing. This medical checklist is used to prove equivalence between the three configurations. Moreover, at a validation stage, Compressed Sensing algorithm was tested in vivo, comparing the acquisition with and without undersampling.
The images were rated similar when comparing the three configurations and no additional artifacts were found due to the new characteristics implemented; so, acceptance criteria were met and performance data demonstrate that the subject device is as safe and effective and is substantially equivalent to the Predicate Device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Listed below are the non clinical tests performed in support of this Submission 510(k) on the MROpen Evo device (models 03-2000-00 and 03-4000-00), in particular:

1. the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
2. electrical safety and electromagnetic compatibility;
3. software verification and validation;
4. the shelf life of the device;
5. performance and safety;
6. usability.

BIOCOMPATIBILITY
A biological evaluation of the materials that come into contact with the patient and/or the user was carried out in compliance with the requirements of the reference standard ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
According to this standard, MROpen Evo is a surface-contacting device and the contact duration is a "limited exposure" (A).
The patient can come into contact with the superficial parts of the receiving coils, made of ABS, that constitute the device and with the fabric covered in plastic/synthetic material of support cushions, through the intact skin surfaces of various areas of the body.
In order to demonstrate the biological safety of the device, tests were conducted to evaluate the endpoints of cytotoxicity, sensitization and irritation on materials in contact with intact skin of patients in accordance with the following FDA-recognized technical standards:
- ISO 10993-5: 2009 (Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity);
- ISO 10993-10: 2010 (Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization);
- ISO 10993-23: 2021 (Biological evaluation of medical devices - Part 23: Tests for irritation).

Testing results in the following table confirm that the samples tested in their finished form can be considered:

- Not cytotoxic
- Not irritant
- Not sensitizing

and no additional testing are required.

ELECTRICAL SAFETY AND EMC
In order to demonstrate the EMC and Electrical safety of the MROpen Evo device, ASG Superconductors S.p.A. has performed tests in compliance with the standards below:

- IEC 60601-1:2005 + A1:2012 + A2:2020 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance);
- IEC 60601-1-2:2015 + A1:2020 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -Requirements and tests);
- IEC 62471: 2006 (Photobiological safety of lamps and lamp systems).

Testing results are positive and no "fail" result appears on the test reports.

SOFTWARE VERIFICATION AND VALIDATION
The life cycle assessment of the MR-GUI PRO software in the current revision was carried out according to the requirements of the IEC 62304:2006 + A1:2015 standard (Medical device software - Software life cycle processes). Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff relevant to the software: "Content of Premarket Submissions for Device Software Functions".
To evaluate MROpen Evo software performances, ASG Superconductor S.p.A. has produced Unit tests and System and Integration test on SW release 3.1.0 and 3.1.1. With the adoption of the MR GUI-PRO software release 3.1.0 and 3.1.1, the image reconstruction technique called Compressed Sensing (CS) for 2D and 3D is introduced. CS is a method to speed up MRI acquisition by acquiring less data through subsampling of k-space.
All test results are Passed because they met the expected results: the introduction of CS software module shows limited recontruction

errors and does not introduce artefacts in image processing compared to standard processing that does not use this reconstruction algorithm. The analysis of results showed that predicate and MROpen Evo software performances are substantially equivalent.

PERFORMANCE AND SAFETY
ASG Superconductor S.p.A. also carried out performance and safety tests on the device MROpen Evo in conformity with the requirements of the standard IEC 60601-2-33:2010 + A1:2013 + A2:2015 (Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis).
In particular, performance tests were conducted in order to evaluate the following endpoints:
- Acoustic Noise
- Unchanged electromagnetic characteristic of inner part of the magnetic unit
- Gradient output
- Specific Absorption Rate (SAR)
- Dynamic forces on patient support
The analysis of performance data demonstrates that the subject device and the legally marketed Predicate Device performances are substantially equivalent for the assessed endpoints.

USABILITY
Regarding the usability of the device MROpen Evo, tests were carried out in conformity with the requirements of the standards below:
- IEC 60601-1-6:2010 + A1:2013 + A2:2020 (Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability);
- IEC 62366-1:2015 + A1: 2020 (Medical devices - Part 1: Application of usability engineering to medical devices).
Testing results are positive and no “fail” result appears on the test reports. This demonstrates that the subject device MROpen Evo is as safe and effective and is substantially equivalent to the legally marketed Predicate Device.

CONCLUSIONS
Concerning the technical characteristics, it has been demonstrated that the subject device is substantially equivalent to the Predicate Device. Then, the non-clinical data support the safety and the substantial equivalence of the device with the predicate. The hardware and software verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Performance data demonstrate the device is substantially equivalent to the legally marketed Predicate Devices.
Therefore, refer to the technical and performance comparison, hazard analysis and performance test aspects, it is demonstrated that MROpen Evo is substantially equivalent and can be considered as safe and as effective as the Predicate Device.