ASG Superconductors S.p.A.
% Luisella De Benedetti
QA/RA Consultant
Corso Ferdinando Maria Perrone 73/R
Genova, 16152
ITALY

December 20, 2019

Re: K193116
Trade/Device Name: MRopen EVO
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: November 4, 2019
Received: November 12, 2019

Dear Luisella De Benedetti:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193116

Device Name
MRopen EVO

Indications for Use *(Describe)*

MRopen EVO is a diagnostic total body imaging device with the following limitation: no cardiac imaging, no breast imaging. MRopen EVO tomograph produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the body. The examinations may be performed both in weight free (supine or seated position) and weight bearing position. The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (Tl), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

9. 510(k) Summary (21 CFR 807.92)

Date: (month/day/year) 11/04/2019

807.92(a)(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

Submitter Information

Name	ASG Superconductors S.p.A.
Address	Corso Perrone 73R - 16152 Genova, Italy
Telephone n.	+39 010 6489 358
Contact Person	Luisella De Benedetti ASG Superconductors S.p.A. Corso F.M. Perrone 73R 16152 Genova +39 010 6489 358 debenedetti.luisella@as-g.it

807.92(a)(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Name of the device	MRopen EVO
Trade name	ASG Superconductors
Classification name	Total Body Magnetic Resonance Diagnostic Device
Classification and class of device	21 CFR 892.1000, class II
Classification Number	90LNH

807.92(a)(3) An identification of the legally marketed device to which the submitter claims equivalence.

PREDICATE (for all items excluded the below specified)
ASG Superconductors S.p.A. MRopen 0.5T K190524

807.92(a)(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

Like the previously cleared device K190524, the actual MRopen EVO is a total body magnetic resonance imaging device characterized by high homogeneity Open-sky Magnet, based on high temperature cryogenless superconductive proprietary technology. The magnet is "U" shaped with the opening upwards to host the patient preventing claustrophobic reactions. The pole plates limit laterally the FOV.

Modification of K190524 cleared device.

- New commercial name (hence labeling is amended)
- Different cover colours from light blue to grey
- Changes in labelling due to above changes

MRopen EVO is a diagnostic total body imaging device with the following limitation: no cardiac imaging, no breast imaging. MRopen EVO tomograph produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the body. The examinations may be performed both in weight free (supine or seated position) and weight bearing position. The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (Tl), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

The modification reflected in this Special 510(k) for the MRopen EVO Tomograph are detailed in below table.

- New commercial name (hence labeling is amended)
- Different cover colours

807.92(a)(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled;

MRopen EVO product is a Magnetic Resonance Diagnostic Device like previous K190524 MRopen 0.5 T model.

MRopen EVO product is Total Body MRDD with the following limitation: no cardiac imaging, no breast imaging like previous K190524 MRopen 0.5 T model.

MRopen EVO Tomograph produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the anatomies. The examinations may be performed both in weight free (supine) and weight bearing position like previous K190524 MRopen 0.5 T model.

The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (Tl), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

Intended population is for Patients less than 200 Kg

The MRopen EVO Tomograph, like previous K190524 MRopen 0.5 T model, can perform DWI images based on a Diffusion excitation pattern applied on a specific acquisition sequence, in this case the HASTE readout sequence. DWI is a well known diagnostic technique which does not rise safety and effectiveness issues different form the previously addressed ones when used as labeled.

In next page we include the IFU statement from K190524 MRopen 0.5 T predicate device.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190524 K190524

Device Name
MRopen 0.5 T

Indications for Use *(Describe)*
MRopen 0.5 T is a diagnostic total body imaging device with the following limitation: no cardiac imaging, no breast imaging. MRopen 0.5 T tomograph produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the body. The examinations may be performed both in weight free (supine or seated position) and weight bearing position. The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

807.92(a)(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section

Technological Characteristics

The MRopen EVO MRI system is substantially equivalent to MRopen 0.5 T K190524 except commercial name and cover colours.

General item	MRopen EVO	Predicate K190524 MrOpen 0.5 T
Anatomical regions	Total body with the following limitation: no cardiac imaging, no breast imaging.	
Nucleus excited	Proton (hydrogen nucleus)	
Diagnostic uses	Magnetic Resonance Diagnostic Device	
SCOUT Multiplanar Ortogonal (SE o GFE)	Yes	
Spin echo T1 (SET1)	Yes	
Spin echo T2 (SET2)	Yes	
Short TE spin echo (ERASE)	Yes	

General item	MRopen EVO	Predicate K190524 MrOpen 0.5 T
Double echo (DE) Inversion recovery (IR)	Yes	
Short TAU inversion recovery (STIR)	Yes	
Short time inversion recovery gradient field echo (GFE-STIR)	Yes	
Gradient Field Echo (GFE)	Yes	
Gradient Field Echo 3D (3D-GFE)	Yes	
RF spoiled gradient echo 3D (3D-SPGFE)	Yes	
Time reversed 3D gradient Field Echo (3D-EMIT)	Yes	
Rapid Imaging SE T2 (RISE)	Yes	
Rapid Imaging DE (RIDE)	Yes	
Fast Inversion Recovery (FIR)	Yes	
FLAIR – Fluid attenuated Inversion Recovery	Yes	
Spin Echo Presat – FAST RISE9 PRESAT	Yes	
Fast Rise (up to 16 echoes)	Yes	
Fast PD (Fast proton density)	Yes	
3D Gradient Balanced Steady State (3D-GBASS)	Yes	
Fat-Water separation T1 (FWS T1)	Yes	
ANGIO sequences	Yes	
HASTE sequence	Yes	
DWI technique	Yes	
Magnetic system	High homogeneity Open-sky Magnet, based on high temperature cryogenless superconductive, horizontal field	
	Maximum Magnetic field 0.5 Tesla	
	Current 146A	
	28000 kg	
	200x200x170 cm (HxDxW)	

General item	MRopen EVO	Predicate K190524 MrOpen 0.5 T
	4.0 x 4.6 x 3.6 m (Vertical x Transversal x Longitudinal)	
	<2 ppm FWHM over 30 cm DSV	
Gantry	56 cm lateral gap	
Gradient System	20mT/m	
	0.6 msec (from 0 – 20 mT/m)	
	33 mT/m/ms	
RF amplifier	9 kW	
	Analogic AN8102 or RFT RF9200 model as alternative	
Spectrometer	ACS MRIBox	
Covers colour	White	
	3M 1080-S261 Dark Grey	Light blue Pantone 285

Receiving Coils' list	Code#autom. Recogn. digit	MRopen EVO	Predicate K190524 MrOpen 0.5 T
C-Spine	03-2003 #7	✓ available in light blue or dark grey	✓ available in light blue
Shoulder	03-2005 #9	✓ available in light blue or dark grey	✓ available in light blue
Hand	03-2006 #4	✓ available in light blue or dark grey	✓ available in light blue
MP-Loop	03-2010 #8	✓ available in light blue or dark grey	✓ available in light blue
Flex S	03-2011 #12	✓ available in light blue or dark grey	✓ available in light blue
Flex L	03-2012 #13	✓ available in light blue or dark grey	✓ available in light blue
MP_Flat	03-2015 #14	✓ available in light blue or dark grey	✓ available in light blue

Receiving Coils' list	Code#autom. Recogn. digit	MRopen EVO	Predicate K190524 MrOpen 0.5 T
Body	03-2019 #2	✓ available in light blue or dark grey	✓ available in light blue
Knee	03-2018#3	✓ available in light blue or dark grey	✓ available in light blue
Head	03-2001#1	✓ available in light blue or dark grey	✓ available in light blue
Head/Neck	03-2020#10	✓ available in light blue or dark grey	✓ available in light blue
Spine	03-2016#8	✓ available in light blue or dark grey	✓ available in light blue
Long Spine	03-2100#11	✓ available in light blue or dark grey	✓ available in light blue
Shoulder	03-2101#9	✓ available in light blue or dark grey	✓ available in light blue

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

Being the proposed changes only referred to Commercial name and colours we do not consider necessary performing new testing with respect to those attached to K190524 cleared file.

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific

reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

Being the proposed changes only referred to Commercial name and colours we do not consider necessary performing new testing with respect to those attached to K190524 cleared file.

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

Being that proposed change doesn't affect performance of the device we conclude that the non clinical (bench) and clinical (healthy volunteers) data supplied within K190524 file demonstrate both MRopen 0.5T and MRopen EVO to be as safe, as effective and that it also performs as well than the predicate. Mropen EVO is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards being different just in name and in colours from the predicate MRopen 0.5 T K190524.