ASG Superconductors S.p.A.
% Luisella De Benedetti
Quality and Regulatory Affairs
Corso Ferdinando Maria Perrone 73/R
Genova, 16152
ITALY

July 1, 2019

Re: K190524
Trade/Device Name: MRopen 0.5 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: May 14, 2019
Received: May 31, 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

ASG
SUPERCONDUCTORS

6. Statement of Indications for Use (form 3881)

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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 (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.

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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."

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7. 510(k) Summary (21 CFR 807.92)

Date: (month/day/year) 05/14/2019

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 0.5 T
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

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

PRIMARY PREDICATE (for all items excluded the below specified)

Paramed S.r.l	MrOpen	K151466

SECONDARY PREDICATE (FOR DWI-HASTE APPLICATION)

Siemens	Magnetom C!	K082331

SECONDARY PREDICATE (FOR Compressors)

Siemens	AVANTO	K032428

SECONDARY PREDICATE (FOR Spectrometer and shoulder coil)

Paramed S.r.l	MrJ 3300	K122034

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 K151466, the actual MRopen 0.5 T 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 K151466 cleared device.

- Introduce DWI technique based on HASTE readout sequence
- Introduce internally developed User Interface
- Introduce changes in hardware such as spectrometer, compressors and cold heads, RFA
- Introduce change in hardware inside the magnet (double current same magnetic field, same superconductive MgB_2 wire, less coils)
- Long Spine receiving coil
- Shoulder coil new model
- Changes to patient support shapes and courtesy cushions

MRopen 0.5 T is indicated for use as 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.

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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 Traditional 510(k) for the MRopen 0.5 T Tomograph are to introduce updates in hardware and software including the DWI technique previously not released. The modifications have not altered the scientific technology of the unmodified version MrOpen K151466 as detailed in below table.

Claimed Feature	Discussion
Introduce DWI technique based on HASTE readout sequence	This sequence has been introduced to complete the sequence package of the MRopen 0.5 T tomograph, now that the updated hardware and software grant better image quality results. Here the referred predicate is Siemens Magnetom C! K082331 Bibliography is supplied regarding this well-known technique
Introduce internally developed User Interface	After many years of development it is possible to release this user interface which is completely internally designed and excludes legacy software or software developed prior to IEC62304.
Introduce changes in hardware such as:	
spectrometer	This spectrometer already employed for smaller tomograph ASG Superconductors S.p.A. K122034 grants more flexibility to the new software granting DWI technique performance
Compressors and cold heads	We intend to adopt as an alternative (to Leybold ones) for servicing and for newly designed device the Sumitomo F70H compressor models already in use with Siemens AVANTO K0322428 predicate. CH-210 Cold Head are indicated to be used together with F70H compressors. Both compressors and Cold Heads are declared conformant to IEC 60601-1 by Sumitomo
RFA	We intend to adopt as an alternative (to Analogic Corp.) for servicing and for newly designed devices the RFT RF9200 9KW model
Introduce change in hardware inside the magnet (double current same magnetic field)	ASG superconductors decided to double the current inside the magnet while keeping unchanged the magnetic field to reduce the number of superconductive coils inside the vacuum chambers and this results in a cost reduction due to less MgB_2 wire. • No change in material which is the same MgB_2 manufactured within ASG Superconductors S.p.A. Columbus Wire Business Unit • No change in supplier manufacturing process • Completely owned proprietary magnet construction process
Long Spine receiving coil	This receiving coil is equivalent to standard Spine coil in K151466 designed to fit a longer column segment. It allows performing exams on adjacent sections of the spine without moving the coil under the patient

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	back, but just adjusting patient table position inside the magnet isocenter.
Shoulder coil	This new model is derived from MrJ 3300 predicate device K122034 and it will be employed together with the new patient comfort accessories supplied
Patient comfort accessories	Some new cushion shapes and supports have been studied to improve comfort during shoulder and head exams (no new materials and technologies)

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 0.5 T product is a Magnetic Resonance Diagnostic Device

MRopen 0.5 T is Total Body MRDD 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 anatomies. The examinations may be performed both in weight free (supine) 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.

Intended population is for Patients less than 200 Kg

The new MRopen 0.5 T Tomograph can perform DWI images based on a Diffusion excitation pattern applied on a specific acquisition sequence, in this case the HASTE

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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.

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 0.5 T MRI system is substantially equivalent to

General item	**MRopen 0.5 T**	**Primary Predicate K151466 MrOpen**	**Secondary Predicate Siemens Magnetom C! K082331**
Anatomical regions	Total body with the following limitation: no cardiac imaging, no breast imaging.	Total body with the following limitation: no cardiac imaging, no breast imaging.	Total Body
Nucleus excited	Proton (hydrogen nucleus)		
Diagnostic uses	Magnetic Resonance Diagnostic Device		
SCOUT Multiplanar Ortogonal (SE o GFE)	Yes	Yes	
Spin echo T1 (SET1)	Yes	Yes	
Spin echo T2 (SET2)	Yes	Yes	
Short TE spin echo (ERASE)	Yes	Yes	
Double echo (DE) Inversion recovery (IR)	Yes	Yes	
Short TAU inversion recovery (STIR)	Yes	Yes	

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General item	MRopen 0.5 T	Primary Predicate K151466 MrOpen	Secondary Predicate Siemens Magnetom C! K082331
Short time inversion recovery gradient field echo (GFE-STIR)	Yes	Yes	
Gradient Field Echo (GFE)	Yes	Yes	
Gradient Field Echo 3D (3D-GFE)	Yes	Yes	
RF spoiled gradient echo 3D (3D-SPGFE)	Yes	Yes	
Time reversed 3D gradient Field Echo (3D-EMIT)	Yes	Yes	
Rapid Imaging SE T2 (RISE)	Yes	Yes	
Rapid Imaging DE (RIDE)	Yes	Yes	
Fast Inversion Recovery (FIR)	Yes	Yes	
FLAIR – Fluid attenuated Inversion Recovery	Yes	Yes	
Spin Echo Presat – FAST RISE9 PRESAT	Yes	Yes	
Fast Rise (up to 16 echoes)	Yes	Yes	
Fast PD (Fast proton density)	Yes	Yes	
3D Gradient Balanced Steady State (3D-GBASS)	Yes	Yes	
Fat-Water separation T1 (FWS T1)	Yes	Yes	
ANGIO sequences	Yes	Yes	

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General item	MRopen 0.5 T	Primary Predicate K151466 MrOpen	Secondary Predicate Siemens Magnetom C! K082331
HASTE sequence	Yes	No	Yes
DWI technique	Yes	No	Yes

General item	MRopen 0.5 T	Primary Predicate K151466 MrOpen
Magnetic system	• High homogeneity Open-sky Magnet, based on high temperature cryogenless superconductive, horizontal field	
	Maximum Magnetic field 0.5 Tesla	
	Current 146A	Current 84 A
	28000 kg	
	200x200x170 cm (HxDxW)	
	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	Analogic model AN8102

General item	MRopen 0.5 T	Secondary Predicate K122034 MrJ 3300
Spectrometer	ACS MRIBox	

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Receiving Coils' list	Code#autom. Recogn. digit	MRopen 0.5 T	Primary Predicate K151466 MrOpen	Secondary Predicate K122034 MrJ 3300
C-Spine	03-2003 #7	✓	✓	
Shoulder	03-2005 #9	✓	✓	
Hand	03-2006 #4	✓	✓	
MP-Loop	03-2010 #8	✓	✓	
Flex S	03-2011 #12	✓	✓	
Flex L	03-2012 #13	✓	✓	
MP_Flat	03-2015 #14	✓	✓	
Body	03-2019 #2	✓	✓	
Knee	03-2018#3	✓	✓	
Head	03-2001#1	✓	✓	
Head/Neck	03-2020#10	✓	✓	
Spine	03-2016#8	✓	✓	
Long Spine	03-2100#11	✓	longer version of 03-2016#8	
Shoulder	03-2101#9	✓		✓

(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;

The MRopen 0.5 T has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, software verification and image quality and has been found to conform to the following medical device safety standards (see also Section 8 Conformance to Consensus Standards and test reports).

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According to our quality management system a report is issued if a standard changes, if the device changes or both. Not all the tests were newly performed where the above conditions did not apply

Standard	**FDA Recog. number**	**Rationale for repeating/not repeating tests**	**510(k) ref**
IEC 60601-1	19-4	Hardware/Software changes Test repeated	See below section 8
60601-2-33 Ed. 3.2 b:2015	12-295	Standard Changed Test repeated	See below section 8
60601-1-2 Edition 4.0 2014-02	19-8	Hardware changes Test repeated	See below section 8
60601-1-6 Edition 3.1 2013-10	5-89	Software/Hardware changes Test repeated	See below section 8
62366-1 Edition 1.0 2015-02	5-114	Software changes Test repeated	See below section 8
62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	13-79	Software changes Test repeated	See below section 8
62471 First edition 2006-07	12-249	No change - Not repeated	K151466
MS-1-2008 (R2014)	12-188	No change - Not repeated	K151466
MS 2-2008 (R2014)	12-19	The standard NEMA MS-2 2008 (R2014) changed introducing the requirement of using a square voxel for the test image. We already fullfilled that requirement and do not need to repeat the test	K151466
MS 3-2008 (R2014)	12-187	No change - Not repeated	K151466
NEMA MS-4	12-232	No change - Not repeated	K151466
NEMA MS-5	12-231	No change - Not repeated	K151466

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MS 6-2008 (R2014)	12-195	New Long Spine coil Test repeated	See below section 8
MS 8-2016	12-315	The Standard NEMA MS-8 2016 differ from the version used for previous 510(k) submission. As stated in the Introduction at pag. v, the modification aim to consider the method adjustement required by higher frequency transmitting coil (125 MHz) used in 3T systems. As the proposed equipment works at a much lower frequency (21 MHz) we evaluate to not repeat the connected test	K151466
MS 9-2008 (R2014)	12-288	New Long Spine coil Test repeated	See below section 8
MS 10-2010	12-298	No change - Not repeated	K151466
NEMA PS 3.1	12-300	Software Changed	See Appendix H

(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

No clinical tests were performed.

We supply images of healthy volunteers who agreed to cooperate to demonstrate performance of the device on humans.

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Only main changes were tested:

Item tested	Result/remarks
New DWI technique base on HASTE readoutsequence	The images on healthy volunteers conform to the expected image quality. Both ADC calculated image and DWI images along the three main directions are displayed
New Long Spine coil	The use of this new receiving coil has been referred to the previous spine model for equivalent or better quality image, with the workflow improvement of not new coil positioning in case of multiple scan of different streches of spine. Performance test report in Section 18
Shoulder coil New model	This design is exactly the same employed in MrJ 3300 secondary predicate device which better fits the new patient comfort accessories during shoulder exam. Performance test report in Section 18

Population (healthy volunteers)
The healthy volunteers were adult male and female aged between 20 and 60 available in our firm.

(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.

The non clinical (bench) and clinical (healthy volunteers) data demonstrate MRopen 0.5T to be as safe, as effective and performs as well than the predicates. Mropen 0.5 T is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.

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