DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Paramed S.r.l.
% Ms. Luisella De Benedetti
Quality Manager
Corso F. M. Perrone 73R
Genoa, 16152
ITALY

October 15, 2015

Re: K151466
Trade/Device Name: MrOpen 05
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: September 7, 2015
Received: September 10, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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MEDICAL SYSTEMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151466

Device Name
MrOpen 05

Indications for Use *(Describe)*
MrOpen 05 is indicated for use as a diagnostic total body imaging device with the following limitation: no cardiac imaging, no breast imaging. MrOpen 05 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.

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

Date: (month/day/year) 05/25/2015

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

Submitter Information

Name	Paramed Srl
Address	Corso Perrone 73R - 16152 Genova, Italy
Telephone n.	+39 010 6489 358
Contact Person	Luisella De Benedetti Paramed S.r.l. Corso F.M. Perrone 73R 16152 Genova +39 010 6489 358 luisella.debenedetti@paramed.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 05
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:

Paramed	MrOpen 0.5T	K101295

SECONDARY PREDICATE (FOR ANGIOGRAPHY APPLICATION)

Toshiba	OPART	K990260

SECONDARY PREDICATE (FOR SPINE COIL USE)

Paramed	Spine COIL	K123708

SECONDARY PREDICATE (FOR MATERIALS)

Paramed	Performance package	K121249

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 K101295, the actual MROpen 05 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 K101295 cleared device.

- Remove the angiography limitation,
- update software by adding a new angiography sequence and 3D viewer tool,
- update the receiving coils' set including some new coils.

MROpen 05 is indicated for use as a diagnostic total body imaging device with the following limitation: no cardiac imaging, no breast imaging. MrOpen 05 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 Traditional 510(k) for the MrOpen 05 Tomograph are to improve system performance. The modifications have not altered the scientific technology of the unmodified version MrOpen 05 K101295.

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 05 product is a Magnetic Resonance Diagnostic Device

MrOpen 05 is Total Body MRDD with the following limitation: no cardiac imaging, no breast imaging.

MrOpen 05 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 05 Tomograph can perform Angiography studies for this reason multiple predicates are addressed. Angiography 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 05 MRI system is substantially equivalent to

General item	**MrOpen 05**	**Primary Predicate K101295 MrOpen 05**	**Secondary Predicate Opart K990260**
Anatomical regions	Total body with the following limitation: no cardiac imaging, no breast imaging.	Total body with the following limitation: no angiography, no cardiac imaging, no breast imaging.	Total Body
Nucleus excited	Proton (hydrogen nucleus)		
Diagnostic uses	Magnetic Resonance Diagnostic Device		
Angiography	Yes	No	Yes

General item	**MrOpen 05**	**Primary Predicate K101295 MrOpen 05**
Magnetic system	• High homogeneity Open-sky Magnet, based on high temperature cryogenless superconductive, horizontal field	
	0.5 Tesla	
	Mechanical	
	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	

Receiving Coils' list	**Code#autom. Recogn. digit**	**MrOpen 05**	**Primary Predicate K101295 MrOpen 05**	**Secondary Predicate Spine coil K123708**
Head	*03-2001-00#1*	*Superseded by 03-2001-01#1*	✓	-
Body	*03-2002-00#2*	*Superseded by* 03-2019-00#2	✓	-
C-Spine	*03-2003-00#7*	✓	✓	-
Knee	*03-2004-00#3*	*Superseded by* 03-2018-00#3	✓	-
Shoulder	*03-2005-00#9*	✓	✓	-
Hand	*03-2006-01#4*	✓	✓	-
MP-Loop	*03-2010-02#8*	✓	✓	-
Flex S	*03-2011-00 #12*	✓	✓	-
Flex L	*03-2012-00 #13*	✓	✓	-
MP_Flat	*03-2015-02#14*	✓	✓	-
Spine	*03-2016-00#8*	✓	-	✓
Body	03-2019-00#2	✓	Predicate code 03-2002-00	-
Knee	03-2018-00#3	✓	Predicate code 03-2004-00	-
Head	03-2001-01 #1	✓	Predicate code 03-2001-00	-
Head/Neck	03-2020-00#10	✓	Predicate code 03-2001-00	-

(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 05 has been evacuated 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 3654 Forms).

According to our quality management system a report I 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	Standard revision - repeated	See below section 8
IEC 60601-2-33	12-271	Standard revision - repeated	See below section 8
IEC 62304	13-8	Software changes – repeated	See below section 8
IEC 62471	12-249	No change - Not repeated	K101295
NEMA MS-1	12-188	New coils - repeated	See below section 8
NEMA MS-2	12-196	No change - Not repeated	K101295
NEMA MS-3	12-187	New coils - repeated	See below section 8
NEMA MS-4	12-232	No change - Not repeated	K101295
NEMA MS-5	12-231	No change - Not repeated	K101295
NEMA MS-6	12-195	No single channel new coils - Not repeated	K101295
NEMA MS-8	12-192	No change - Not repeated	K101295
NEMA MS-9	12-264	No change - Not repeated	K101295
NEMA MS-10	12-158	No change - Not repeated	K101295
NEMA MS-12	12-234	No change - Not repeated	K101295

(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.
Paramed supplies images of healthy volunteers who agreed to cooperate to demonstrate performance of the device on humans.
Only main changes were tested:

Item tested	Result/remarks
New Angiography sequence	The images on healthy volunteers conform to the expected image quality
New coils	The use of this new receiving coils has been referred to the previous models for equivalent or better quality image, or patient comfort

Population (healthy volunteers)
The healthy volunteers were adult male and female aged between 20 and 50 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 to be as safe, as effective and performs as well than the predicates. MrOpen is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.