JUL 28 2010

IEC standards:	IEC 60601-1, International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety IEC 60601-2-33
UL standards:	UL 94 Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
FDA standards:	Regulations under 21 CFR Subchapter J - Radiological Health
Voluntary standards:	DICOM 3.0

A.3.9 510(K) Summary of Safety and Effectiveness

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

Manufacturer Information

Manufacturer:	Paramed Srl
Address:	Corso Perrone 73R 16152 Genova, Italy
Establishment registration number:	3004994584

807.92(a)(1)

Submitter Information

Correspondent: Correspondent	Richard R. Glasheen (from 2010-05-10 on), 39 High Street North Andover, MA 01845 USA. Ph: 978.975.7530 x4345 Fax: 978.975.9930
Contact person:	Richard R. Glasheen (from 2010-05-10 on),

807.92(a)(2)

Trade Name:	MrOpen 05
Common Name:	Total Body Magnetic resonance diagnostic device
Classification Name(s):	System, Nuclear Magnetic Resonance Imaging
Classification and class of device:	21 CFR 892.1000, class II
Classification Number:	90LNH

807.92(a)(3)

Predicate Devices

Paramed	MrOpen	K073362

807.92(a)(5)

Device Intended Use(s)

The intended use of Paramed's MrOpen 05 product is indicated for use as a diagnostic total body imaging device with the following limitation: no angiography, no cardiac imaging, no breast imaging. MrOpen 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.

807.92(a)(6)

Technological Characteristics

The MrOpen 05 MRI system is substantially equivalent to

- Paramed MrOpen K073362 as a total body open structure superconducting MRI Scanner

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Paramed Srl
% Mr. Richard R. Glasheen
Correspondent
39 High Street
NORTH ANDOVER MA 01845

JUL 28 2010

Re: K101295
Trade/Device Name: MR Open 0.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNI
Dated: April 28, 2010
Received: May 10, 2010

Dear Mr. Glasheen:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

k101295

510(k) Number (if known): **k101295**

JUL 28 2010

Device Name: MR Open 0.5T

Indications for Use:

"The MR Open is indicated for use as a diagnostic total body imaging device with the following limitation: no angiography, no cardiac imaging, no breast imaging.

MR Open tomograph produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the body.

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 (TI), 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."

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number k101295