PARAmed
MEDICAL SYSTEMS

K073362

MAY 23 2008

H. Safety and Effectiveness Information

H.1 510(k) Statement – Safety & Effectiveness Letter

Date: 23/11/07

510(k) Status Coordinator
FDA, Center for Devices & Radiological Health (HFZ – 401)
9200 Corporate Blvd.
Rockville, MD 20850

REFERENCE: 510(k) Statement – Safety & Effectiveness Letter
Included with 510(K) Notification
PARAMED SRL

I certify that, in my capacity as Authorized officier of Paramed Srl, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be in a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

All requested information should be directed to the following:

Michael A. Douglas
39 High Street
North Andover,
MA 01845 USA.
Ph: 978.975.7530 x4345
Fax: 978.975.9930

Sincerely,

Gian Enrico Tardivelli, Authorized Officier

Paramed Srl

Paramed s.r.l
Sede Legale e Operativa:
Corso F.M. Perrone, 73r - 16152 Genova
Tel. Fax- ++39 010 7404530
e-mail: info@paramed.it – www.paramed.it

Codice Fiscale e Iscrizione al Registro
delle Imprese di Genova 01195740095
P.IVA 01195740095 – C.C.I.A.A. (REA) Genova 373591
Capitale Sociale € 15 600 I.V.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Paramed Srl
% Mr. Michael A. Douglas
Correspondent
39 High Street
NORTH ANDOVER MA 01845 USA

Re: K073362
Trade/Device Name: MrOpen
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 19, 2008
Received: May 1, 2008

Dear Mr. Douglas:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073362

Device Name: MrOpen

Indications For Use: The MROpen is a total body magnetic resonance imaging device.
It is indicated for use as a diagnostic total body imaging device that 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 (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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073362