PARAmed

K080098

MAR 1 0 2008

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:	To be filed

807.92(a)(1)

Submitter Information

Correspondent:	Michael A. Douglas, 739 High Street North Andover, MA 01845 USA. Ph: 978.975.7530 x4345 Fax: 978.975.9930
Contact person:	Michael A. Douglas

807.92(a)(2)

Trade Name:	MRJ_Extended
Common Name:	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

PARAmed

807.92(a)(3)

Predicate Devices

Paramed MrJ for which the	K033507 for all items excluded the L-spine coils/district of examination
Esaote S-Scan	K063207 is addressed

807.92(a)(5)

Device Intended Use(s)

The MrJ_Extended intended use is the one of the predicate MrJ device (included the restrictions and limitations there claimed) plus the following option:

This device can produce diagnostic images of the L-Spine district using for that purpose an extended FOV and dedicated receipt coils (also the L-spine application is limited by the exclusion of tumor detection application).

807.92(a)(6)

Technological Characteristics

The MRJ_Extended MRI system is substantially equivalent to the currently available Paramed MrJ cleared via K033507 for all items excluded the spine coils for which the and Esaote S-Scan system cleared via K063207 is addressed.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
PARAMED S.R.L

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
JANUARY 08 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
CORSO FM PERRONE 73R
16152 GENOA (ITALY)

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) +39 010 7404530
(Fax) //

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

MODEL MRI-EXTENDED
CODE 01-1872-00

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K080098

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
G.T. Tardivelli

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) GIAN ERICO TARDIVELLI
(Title) AUTHORIZED OFFICIER

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
VIALE FRANCESCO GAMBARO 5/2
16146 GENOA (ITALY)

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 010/7404530
(Fax) 010/7404530

15. DATE OF CERTIFICATION
04 FEB 2008

PSC Graphics (301) 443-1090 EF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Paramed SRL
% Mr. Michael A. Douglas
Correspondent
Paramed Medical Systems
739 High Street
NORTH ANDOVER MA 01845

MAR 10 2008

Re: K080098
Trade/Device Name: MRJ_Extended
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 8, 2008
Received: January 16, 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 (Premarket Approval), 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): K080098

Device Name: MRJ Extended

Indications For Use: The intended use of Paramed's MRJ_Extended product is for diagnostic nuclear magnetic resonance imaging of hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ), C- spine and L-Spine with limitation to joint pathologies (no tumors, no angiography). The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joint being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

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 K080098