JUL 19 2011

510(K) Summary, Special 510(k) K11

K111725

Submitters:

PHILIPS Medical Systems DMC GmbH **Roentgenstrasse 24** **22335 Hamburg** **Germany** **Tel. +49-040 2899 - 0** **Fax: +49-040 2899 - 2002**	**SEDECAL SA** **Pelaya 9- Poligono Industrial Rio De Janeiro** **28110 –Algete** **Madrid Spain** **Tel +34- 91-628 0544/91-628 1592** **Fax +34- 91-628 0574**

Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager, Sedecal SA
Date Prepared: June 10, 2011

1. **Identification of the Device:**
   Proprietary-Trade Name: **MobileDiagnost wDR**
   Classification Name: System, x-ray, mobile, IZL and solid state x-ray imager (flat panel/digital imager), MQB
   Common/Usual Name: Mobile Diagnostic X-ray System with Digital Panel

2. **Equivalent legally marketed devices**:
   - Easy Moving Plus, Mobile Diagnostic X-Ray (K090322) marketed by Sedecal
   - The Detector is identical to the Wireless Portable Detector FD-W17 (K090625) marketed by Philips Medical Systems

3. **Description of the Device**: This device is simply the combination of two cleared devices, the Wireless Portable Detector FD-W17 (K090625) marketed by Philips Medical Systems and the Easy Moving Plus, Mobile Diagnostic X-Ray (K090322) made by Sedecal. The x-ray source is a motor driven mobile x-ray and the x-ray receptor panel is a digital wireless unit. The Wireless Portable Detector FD-W17 consists of three main parts:
   - Portable radiography detector (x-ray sensitive part)
   - docking station which is directly connected to the radiographic workstation
   - backup cable which can connect the detector to the docking station if the wireless connection cannot be used.

   Detector size: 35 x 43 cm (14 x 17") Image matrix size: 3000 pixels x 2400 pixels.
   Pixel size 144 µm, Image resolution up to 3.5 LP/mm

4. **Indications for Use** (intended use): Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

5. **Safety and Effectiveness, comparison to predicate device**. This modified device has the same indications for use and technological characteristics as the predicate devices, in fact employing the predicate devices in the end product.

6. **Description of Testing:** Clinical images were acquired and compared to our predicate images. There were no significant differences between them. We also performed software validation testing. The results of clinical, bench, safety test, and software validation testing indicates that the new device is as safe and effective as our predicate device. The modified device conforms to US Performance Standards and the hardware is CSA Certified compliant to US Standards for safety for medical devices.

7. Substantial Equivalence Chart

Characteristic	Sedecal Easy Moving Digital K090322	MobileDiagnost wDR
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)	SAME
Configuration	Battery or line operated mobile	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Generator power levels	20 to 50 kw (4 models)	20 to 50 kw (4 models)
Collimator	Ralco R221 DHHS	Ralco 108F DHHS -equivalent
Image acquisition	Digital CANON CDXI-50G K031447	Philips Wireless Portable Detector FD-W17 K090625
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

8. **Conclusion:** After analyzing risk analysis, software validation, safety testing data, and clinical images, it is the conclusion of Sedecal that the MobileDiagnost wDR is as safe and effective as the predicate devices, have almost no technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate devices.

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

Sedecal SA
% Ms. Jennifer Cartledge
VP Product Development and Program Management
REU Associates, Inc.
409 Woodridge Dr
SENECA SC 29672

JUL 19 2011

Re: K111725
Trade/Device Name: MobileDiagnost wDR
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL and MQB
Dated: June 16, 2011
Received: June 20, 2011

Dear Ms. Cartledge:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K11_____

Device Name: MobileDiagnost wDR

Indications For Use:

Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. Not intended for mammography.

Prescription Use _X_ **AND/OR** **Over-The-Counter Use** ___.
(Part 21 CFR 801 Subpart D) **(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

510K K111725