



September 18, 2014

Sedecal SA  
% Ms. Jennifer Cartledge  
Consultant  
REU Associates Inc.  
409 Woodridge Drive  
SENECA SC 29672

Re: K141895  
Trade/Device Name: Mobile Diagnost wDR 2.0  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobile x-ray system  
Regulatory Class: II  
Product Code: IZL, MQB  
Dated: August 18, 2014  
Received: August 19, 2014

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. 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,



for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K141895

Device Name

MobileDiagnost wDR 2.0

Indications for Use (Describe)

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 for mammography

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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## 7 510(k) Summary

### 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Manufacturer: SEDECAL SA  
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28110 Algete, Madrid  
Spain (España)  
Establishment registration number:9617251

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Device Name: *MobileDiagnost wDR 2.0*

Classification: (Primary) Product code IZL  
(Primary) Classification Name: Mobile X-Ray System  
(Primary) Classification Regulation: 21CFR 892.1720  
Classification Panel: Radiology  
Device Class: Class II

Predicate Device: Trade Name: *MobileDiagnost wDR*  
Manufacturer: Sedecal SA  
510(k) Clearance: K111725 - July 19, 2011  
(Primary) Product code IZL  
(Primary) Classification Name: Mobile X-Ray System  
(Primary) Classification Regulation: 21CFR 892.1720  
(Secondary) Product code: MQB  
(Secondary) Classification Name: Stationary x-ray system  
(Secondary) Classification Regulation: 21CFR 892.1680  
Classification Panel: Radiology  
Device Class: Class II

Device description: The *MobileDiagnost wDR 2.0* system is a motorized mobile radiographic system consisting of a mobile base unit, and a user interface (computer, keyboard, display, mouse), combined with a flat solid state X-ray detector. It is used by the operator to generate, process and handle digital X-ray images. The *MobileDiagnost wDR 2.0* integrates a new generation of wireless portable x-ray detectors (*SkyPlate*) to replace the former detector WPD FD-W17 cleared under the predicate submission (K111725).

Indications for Use: The Indication for Use of the *MobileDiagnost wDR 2.0* is identical to that of

Use: the currently marketed and predicate device, *MobileDiagnos wDR*, K111725 –July 19, 2011, and is as follows:  
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 for mammography.

Fundamental Scientific Technology: The *MobileDiagnos wDR 2.0* employs the same basic construction and fundamental scientific technology as provided with the currently marketed and predicate device, *MobileDiagnos wDR*, K111725 –July 19, 2011, with regards to the functionality of the following: image receptor type, image processor, automatic image processing, manual image processing, advanced image processing, image export (interfaces), and the use of standard monitors. The new SkyPlate detectors employ the same basic construction and fundamental scientific technology as provided with the detector integrated into the currently marketed predicate device. The proposed MobileDiagnost wDR 2.0 employs the same basic construction and fundamental scientific technology as provided with the currently marketed and predicate device, MobileDiagnost wDR (K111725). With the exception of the detector of the proposed MobileDiagnost wDR 2.0, the mobile base unit is equivalent in comparison with the currently marketed and predicate, MobileDiagnost wDR. As stated in the premarket notification, the integration of the new SkyPlate detector did not necessitate or cause any modification in

- the x-ray tube,
- the x-ray generator,
- the x-ray control, or
- the collimator of the MobileDiagnost wDR 2.0.

Additionally, the software modifications for this submission are only made to ensure proper integration of the new detector in accordance with CDRH’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

The design features of the major components of the currently marketed and predicate MobileDiagnost wDR detector (K111725), which include X-ray absorber, thin film transistor, scintillator and image processor are equivalent to the new SkyPlate wireless portable detectors of the proposed MobileDiagnost wDR 2.0. Additionally, the wireless technology utilized in the currently marketed and predicate MobileDiagnost wDR detector (K111725) is the same as the wireless technology provided with the new SkyPlate detectors of the proposed MobileDiagnost wDR 2.0. The currently marketed and predicate MobileDiagnost wDR device (K111725) offers a detector size of 489 x 466 x 25 mm, while the SkyPlate detectors of the proposed MobileDiagnost wDR 2.0 is provided in both Large: 384 x 460 x 16 mm and Small: 268 x 328 x 16 mm detector sizes. The image size of currently marketed and predicate MobileDiagnost wDR device (K111725) is 3000 x 2400 Pixels, while the SkyPlate detectors of the proposed MobileDiagnost wDR 2.0 is 2330 x 2846 Pixels for the large and 1500 x 1920 Pixels for the small. Finally, the X-ray field of the currently marketed and predicate MobileDiagnost wDR device (K111725) is 432 x 341.1 mm as compared to X-ray fields of 344.8 x 421.2 mm and 222.0 x 284.1 mm provided with the Large and Small Sky-

Plate detectors, respectively, of the proposed MobileDiagnost wDR 2.0. The slightly modified specifications of the additional design features, such as detector size, detector weight, image, Pixel size, etc. of the new SkyPlate wireless portable detectors do not affect the safety or effectiveness of the device since it does not affect the image quality. Regarding the major components of x-ray systems as per 21 CFR 1020.30(a), only the collimator was replaced with an equivalent type from the same manufacturer with almost identical specifications. The following attributes of the equivalent collimator (R221 A DHHS) provided with the proposed MobileDiagnost wDR 2.0 are identical to the collimator, (R108F DHHS), provided with the currently marketed and predicate MobileDiagnost wDR device (K111725): the Field Type, Additional Variable Filtration, Light Source, SID Measurement, Mounting of DAP Chamber, Minimum Inherent Filtration (Al Equivalent), cCSAus Certification, DHHS Certification, Proximity Sensor, X-Ray Rating, Power Supply, and Multilayer Square specification. The equivalent collimator does provide an additional Centering Light option for the Image Receptor Alignment and an Automatic Centering with Metal Flange option for the Alignment to Focus and eliminates the option for a Plastic -120° Flange. Apart from these minor differences, the specification of the replacement collimator is identical to that of the predicate collimator and therefore, does not raise any new issues of safety or effectiveness. Additionally, the alignment and collimation procedures of the proposed MobileDiagnost wDR 2.0 remain identical to that of the currently marketed and predicate MobileDiagnost wDR (K111725).

Note, both the proposed MobileDiagnost wDR 2.0 and the currently marketed and predicate MobileDiagnost wDR device (K111725) use wireless technology for image acquisition and the transmission of images to archive systems and provide patient and exam information from radiology information systems (RIS), but will still be able to utilize CR or traditional film cassettes as a back-up scenario.

Based on the information provided above, the *MobileDiagnost wDR 2.0* is considered substantially equivalent to the currently marketed and predicate device, *MobileDiagnost wDR*, K111725 –July 19, 2011 in terms of fundamental scientific technology.

Summary of  
Non-Clinical  
Performance  
Data:

The non-clinical performance testing constrains that the main physical values for comparison of X-ray devices like DQE and MTF are basically equal or better than the predicate device ranging from 61% to 14% for MTF (predicate 60% to 15%) and from 66% to 24% for DQE (predicate 66% to 22%).

The non-clinical performance data demonstrate substantial equivalence. They include (but are not limited to):

- Detective Quantum Efficiency (DQE)
- Modulation Transfer Function (MTF)
- Aliasing
- Output signal level
- Lag, Memory Effects and Ghost Images
- Allowable types and quantity of defects
- Change in detection sensitivity

- Latent image decay characteristic
- Recovery time for radiographic devices
- Dose requirements and reciprocity changes
- Stability of device characteristics
- Uniformity of device characteristics
- Reuse rate for radiographic devices
- Test pattern image tests

The *MobileDiagnos wDR 2.0* complies with the following international and FDA-recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes
- AAMI/ANSI IEC 62366 Application of usability engineering to medical devices
- ISO 14971 Application of risk management to medical devices
- ANSI/AAMI ES60601-1 Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-3 Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment
- IEC 60601-2-54 Medical Electrical Equipment - Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy
- IEC 62220-1 ME equipment - Part 1-2: Determination of the detective quantum efficiency
- NEMA PS 3.1 - 3.20 Digital Imaging And Communications In Medicine (DICOM) Set
- ISO 10993-1 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

Non-clinical software verification and validation tests have been performed with regards to the intended use, technical claims, requirements specifications and risk management results.

The non-clinical software verification and validation test results demonstrate that the *MobileDiagnos wDR 2.0* complies with international and FDA-recognized consensus standards and meets the acceptance criteria and is adequate for its intended use. Therefore, the *MobileDiagnos wDR 2.0* is substantially equivalent to the currently marketed device, *MobileDiagnos wDR, K111725* –July 19, 2011 in terms of safety and effectiveness.

Summary of  
Clinical Data:

No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing is sufficient to assess the device safety and effectiveness, including demonstrating equivalent image quality. However, as part of design validation, clinical images were collected and analyzed, to ensure that images constructed by the modified system meet user needs, as per 21 CFR 820.30(g) “Design Validation”. This study consisted of a single blinded, concurrence study, according to CDRH’s *Guidance for the Submission of 510(k)’s for*

*Solid State X-ray Imaging Devices.* The study confirmed that the new x-ray detectors, *SkyPlate*, meet user needs and provide images of equivalent diagnostic capability to the predicate device, the WPD FD-W17 detector cleared under K111725 with the *MobileDiagnos wDR* –July 19, 2011, meeting all requirements regarding substantial equivalence pertaining to user needs.

Substantial  
Equivalence  
Conclusion:

The *MobileDiagnos wDR 2.0* is substantially equivalent to the currently marketed and predicate device *MobileDiagnos wDR*, K111725 –July 19, 2011 in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Furthermore, The new portable x-ray detectors *SkyPlate* have already received a 510(k) market clearance under K133259 on January 24, 2014 (integrated into the Siemens *Ysio Max* x-ray system), under K141381 on June 12, 2014 (integrated into the Philips *DuraDiagnost* radiography system), and under K141736 on July 25, 2014 (integrated into the Philips *ProGrade* and Philips *Eleva Workspot for DigitalDiagnost*). Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304, IEC 62366, ISO 14971, ES60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54, IEC 62220-1, and NEMA PS 3.1 - 3.20 and ISO 10993-1.

The results of these tests demonstrate that *MobileDiagnost wDR 2.0* met the acceptance criteria and are adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, software validation, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.