Sedecal 510(k) Summary
510(k) Number K130883

APR 1 8 2013

1. **Submitter:**
   SEDECAL SA
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   Date Prepared: April 5, 2013
   Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

2. **Identification of the Device:**
   Proprietary-Trade Name: Sedecal Digital Radiographic Upgrade Model SDRU-T
   Classification Name: Stationary x-ray system
   Common/Usual Name: Stationary x-ray system
   Regulation Number: 21 CFR 892.1680
   Product Code: MQB)

3. **Equivalent legally marketed device**: This device uses the same digital x-ray panels as:
   Meridian Medical Universal Digital Interface UDI 1717, K112527 **OR**
   Meridian Medical Universal Digital Interface Wireless – UDI 1417W, K111305
   and uses the same software as the Medicatech Krystalrad 660, K112132.

4. **Description of the Device**: This Digital Radiographic Upgrade is intended for those radiographic examination rooms where the X-ray image receptors used are Cassette with Film or CR. This upgrade allows to acquire digital medical diagnostic X-ray images and transfer the images to hardcopy, softcopy, and archive devices on the same network. Some functions allowed with the Digital Radiography Operator Console (DROC) software:
   - Add new patients to the system, enter information about the patient and physician that will be associated with the digital radiographic images.
   - Edit existing patient information.
   - Emergency registration and edit Emergency settings.
   - Pick from a selection of procedures, which defines the series of images to be taken.
   - Adjust technique settings before capturing the X-ray image.
   - Preview the image, accept or reject the image entering comments or rejection reasons to the image. Accepted images will be sent to the selected output destinations.
   - Save an incomplete procedure, for which the rest of the exposures will be made at a later time.
   - Close a procedure when all images have been captured.
   - Review History images, resend and reprint images.
   - Re-exam a completed patient.
   - Protect patient records from being deleted by the system.
   - Delete an examined Study with all images being captured.
   - Edit user accounts.
   - Check statistical information.
   - Image QC.
   - Image stitching.

5. **Indications for Use (intended use)** Sedecal Digital Radiographic Upgrade Model SDRU-T is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

6. **Technological Characteristics**: This device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. Specifications are for all intents and purposes identical. This submission represents the combination of two cleared devices: Software, and Digital X-Ray panel.

7. **Discussion of the nonclinical and clinical tests in the premarket notification submission for a determination of substantial equivalence:** We performed electrical safety (IEC 60601-1), electromagnetic compatibility testing, (IEC 60601-1-2), software validation testing, and testing. Test images were acquired and evaluated based on the FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices. Clinical testing is not required because the digital panel was already cleared but images were acquired for verification/validation purposes. They were evaluated and found to be of good diagnostic quality.

8. **Conclusion**. Based on the results of the nonclinical tests (that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed devices) we conclude that this new digital x-ray upgrade kit is safe and effective as the predicates identified in paragraph (3). Furthermore, the materials and construction methods are nearly identical to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 18, 2013

SEDECAL SA
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25TH STREET NW
BUFFALO MN 55313

Re: K130883
Trade/Device Name: Sedecal Digital Radiographic Upgrade Model SDRU-T
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 28, 2013
Received: March 29, 2013

Dear Mr. Job:

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 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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): K130883

Device Name: SEDECAL DIGITAL RADIOGRAPHIC UPGRADE, Model: SDRU-T

Indications for Use:

Sedecal Digital Radiographic Upgrade Model SDRU-T is intended for digital image capture use in general radiographic examinations, wherever conventional screenfilm systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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