MAR 2 1 2014

Sedecal Special 510(k) Summary
510(k) Number K133782

1. **Submitter:**
SEDECAL SA
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Date Prepared: March 10, 2014
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

2. **Identification of the Device: Proprietary-Trade Name:**) Sedecal "NOVA FA DR System"
Classification Name: Stationary X-Ray System, Product Codes MQB and KPR
Common/Usual Name: Digital Diagnostic X-Ray System; Regulation 21CFR892.1680

3. **Equivalent legally marketed device**: K090279, Sedecal Millennium Plus Digital Diagnostic X-Ray Systems.

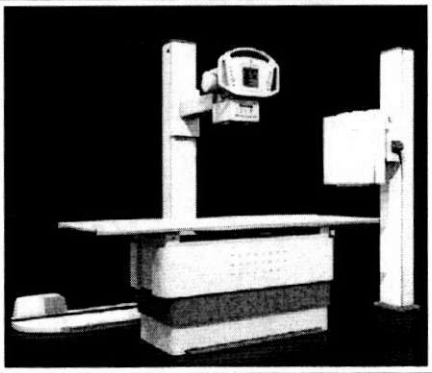
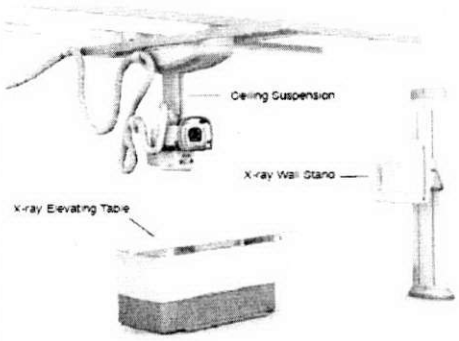
4. **Description of the Device**: "NOVA FA DR System" refers to a full Digital Radiography system consisting of: NOVA: Automatic Ceiling Suspension
NBS: Tilting Vertical Wall Stand system with CXDI Canon Detectors 401C / 401C Compact / 55C / 501C (Option 1)
NET: Elevating Table with CXDI Canon Detector (same detectors as Wall Stand) (Option 2)
Flexi DT: Mobile Elevating Table
SEDECAL SHF Generator Series, output powers: 50 kW / 65 kW / 80 kW
Toshiba Tube: maximum heat dissipation: 300 kHU / 400 kHU
Ralco Collimator: Manual / Motorized

   The new device represents a modification to our system shown in K090279. We have changed the originally supplied column suspension to a ceiling suspension and we are providing newer digital panel detectors. All of the panels have their own clearances:
CXDI Canon Detector 401C / 401C Compact K103591
CXDI Canon Detector 55C / K091436
CXDI Canon Detector 501C K111682

5. **Indications for Use (intended use)** Sedecal "NOVA FA DR System" is 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.

6. **Technological Characteristics**: This device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. Specifications are for all intents and purposes identical. This submission represents the combination of cleared and 510(k) exempt devices. The modifications are shown in the comparison table below.

Comparison Table

Characteristic	Predicate: K090279, Sedecal Millennium Plus Digital Diagnostic X-Ray Systems.	Modified Device: Sedecal "NOVA FA DR System"
Indications Statement	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.	Exactly the same but with the added FDA requested language: (Not for mammography).
Photo		
Digital Receptor Panel	Canon Model CXDI-50G (K060433)	CXDI Canon Detector 401C/401C Compact (K103591) CXDI Canon Detector 55C (K091436) CXDI Canon Detector 501C (K111682)
Panel Resolution	Pixel size 160 × 160 µm Image matrix size 2208 × 2688 pixels Number of pixels Approx. 5.9 million pixels	Pixel size 125 x 125 µm 3,320 x 3,408 pixels (11.3 megapixels) (401C) or 160 x 160 microns 2,208 x 2,688 pixels (approx. 5.9 million pixels) (55C) or Pixel size 125 x 125 µm 2,800 x 3,408 Pixels (9.5 Megapixels) (501C)
Scintillator	GOS Gd_2O_2S:Tb	CsI (CsI: Tl)
Tube Mount	Column Suspension	Ceiling Suspension

7. **Discussion of the nonclinical 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), and software integration testing. Integration testing assured that the unmodified software packages we employed worked together properly. Risk analysis was performed for: the modifications, system integration, the elevating table, generators, mobile table, overhead tube stand, and the wall stand.

8. **Discussion of the clinical testing performed:** Clinical images of various human body structures (chest, skull, abdomen, extremities) were acquired and evaluated by a Board Certified Radiologist and found to be of good quality, high resolution, and clinically acceptable. Techniques employed were comparable to those employed by the predicate panel.

9. **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

March 21, 2014

SEDECAL SA
% Mr. Daniel Kamm, P.E.
Principal Engineer
8870 Ravello Court
NAPLES FL 34114

Re: K133782
Trade/Device Name: NOVA FA DR System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 14, 2014
Received: February 19, 2014

Dear Mr. Kamm:

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 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,

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): K133782

Device Name: Sedecal "NOVA FA DR System"

Indications For Use:
Sedecal "NOVA FA DR System" is 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.

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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