Sedecal, SA.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

October 7, 2020

Re: K202293
Trade/Device Name: Radiographic System Challenge X
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: August 7, 2020
Received: August 13, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202293

Device Name
Radiographic System Challenge X

Indications for Use *(Describe)*
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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: 510(k) Number K202293

SEDECAL SA
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Date Prepared: August 28, 2020
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1) **Identification of the Device:**
Trade/Device Name: Radiographic System Challenge X
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Codes: KPR, MQB.
Common/Usual Name: Digital Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **K133782**
Trade/Device Name: Sedecal "NOVA FA DR System"
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Codes: KPR, MQB.
Common/Usual Name: Digital Diagnostic X-Ray System

3) **Reference devices:** We employ these cleared devices without modification:
Trade/Device Names: Canon Digital X-ray Panels:
- CANON Detector 401C / 401G Compact / (K103591)
- CANON CXDI-401C / 401G Wireless (K133693)
- CANON CXDI-701C / 701G Wireless (K131106)
- CANON CXDI-801C / 801G Wireless (K131106)
- CANON CXDI-710C Wireless (K170332)
- CANON CXDI-810C Wireless (K170332)
- CANON CXDI-410C Wireless (K171270)
- CANON CXDI-402C Wireless (K192632)
- CANON CXDI-702C Wireless (K192632)

Regulation Number: 21 CFR 892. 1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB

4) **Indications for 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.

5) **Description of the Device**: This is a new generation of Ceiling Suspension Radiographic System. This system is characterized by its simple and functional design. Thanks to its vertical and horizontal displacements, the suspension can cover almost all the room positions in which it is installed allowing all radiographic procedures. The system is modular and supports different configurations, such as radiographic system without radiographic table or without Wall Stand.

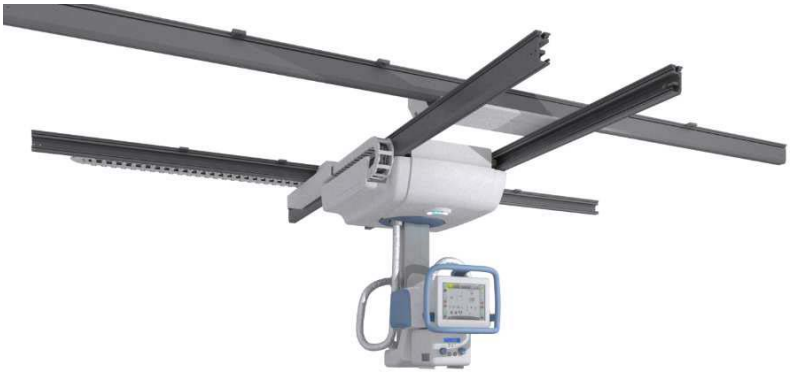
Component Name	Model Number
Radiographic System CHALLENGE X	CHALLENGEX AP
Ceiling Suspension CHALLENGE X	CHAP
Elevating Table NET400	NET400AP
Elevating Table NET500	NET500AP
Wall Stand CHALLENGE X	CHWSAP
X-Ray Generator Console (Wired)	STH

The X-ray image receptors used in this system are digital detectors. X-ray film and Computed Radiography (CR) image receptors can be used but they rarely are these days. The device software used is the CANON CXDI which is supplied unmodified by CANON (Clearance numbers above). It has a moderate level of concern. The Radiographic System **ChallengeX AP** is provided with Auto-positioning, Auto-centering and Auto-tracking functions and it is composed of: Ceiling Suspension (OTC), Radiographic Table, Wall Stand, High Voltage X-ray Generator and acquisition image software. Auto-tracking allows the X-ray Tube to follow the Receptor when it changes position or the other way around while the SID remains constant. The "Auto" features were present and validated in the predicate system.

Overhead Tube Crane (OTC), Challenge X AP:

- Includes the Control Console, X-ray tube and Collimator subassemblies.
- The carriage of the Ceiling suspension contains some electronics and mechanics components and supports the Telescopic column, L-Block Assembly, X-ray Tube Support with the Tube, Collimator and Control Console.
- The telescopic column is composed of four different sized hexagonal tubes of steel. Fixed to the carriage, the telescopic column allows vertical movement of the X-ray tube Assembly in the vertical axis (Z).
- The L-Block Assembly is the junction between the telescopic column and the X-ray tube and collimator assembly. It contains electronic and the mechanical components to allow the movement of the X-ray Tube in the Alpha axis (angulation) and Beta axis (Rotation).
- X-ray Tube support can rotate around its vertical axis of the telescopic column (Beta axis) ± 180º from the position 0º, and it can rotate around its transversal axis (Alpha axis) ± 135º from the position 0º.

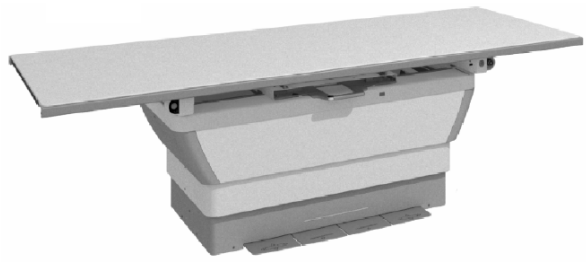
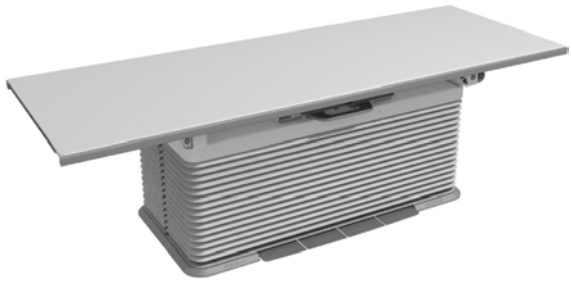
- Control console enables the operator to control the movements of the systems. It is provided with brakes buttons to control each axis movement. The setting of the collimator, X-ray generator and APR are included in the console.



Overhead Tube Crane

RAD Table, model NET400AP or NET500AP:

- It is an elevating table which allows vertical movement and longitudinal/transversal movement of the tabletop (floating movement).
- The elevating table have a control pedals to control the movements.
- The elevating table is provided with a cabinet with a wide range and type of image receptors. Following digital detectors are compatible:
  - CANON digital detectors, models: CXDI-401 C / 401 G Wireless, CXDI-701 C / 701 G Wireless, CXDI-801C / 801G Wireless, CXDI-410C Wireless, CXDI-710 C Wireless, CXDI-810C Wireless, CXDI-402 C Wireless, CXDI-702 C Wireless and CXDI-401C / 401G Compact.
- Optionally the elevating table could be provided with ion chamber for Automatic Exposure Control and anti-scatter grid.

Table NET 500	Table NET 400
	

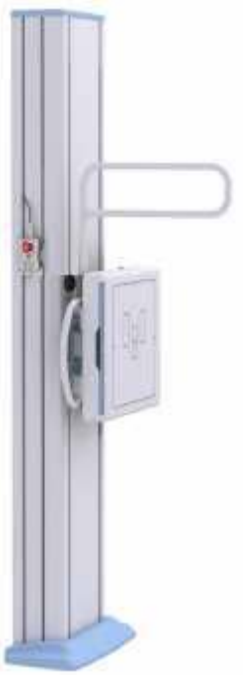
Wall Stand, model CHWSAP:

Wall Stand, model **CHWSAP**, (pictured below) allows vertical movement and tilting / rotational motion of the receptor support assembly. Different versions of Wall Stand are available:

- Only vertical movement.
- Vertical motion and tilting motorized movement.
- Vertical movement, tilting and rotation motorized movement.

The Wall Stand comprises the column, column carriage, image receptor assembly and control movements. The wall stand is counterbalanced to enable a soft vertical movement.

- The column is fixed to the floor and is in charge of holding all the elements. It contains electronic and the mechanical components.
- The column carriage joints the column to the image receptor assembly. By means of the column carriage the image receptor is positioned in desired position. It contains electronical devices for the vertical travel, tilting and rotation functions.
- The image receptor assembly is installed in the support on column carriage. It includes a cassette/detector tray, suitable for all standard cassette and detector sizes. Following digital detectors are compatible:
    - CANON digital detectors, models: CXDI-401 C Wireless, CXDI-701 C Wireless, CXDI-801C Wireless, CXDI-410C Wireless, CXDI-710 C Wireless, CXDI-810C Wireless, CXDI-402 C Wireless, CXDI-702 C Wireless and CXDI-401 Compact.
- The control console placed in the column carriage control the movements of the receptor image.
- Optionally the wall stand could be provided with ion chamber for Automatic Exposure Control and anti-scatter grid.

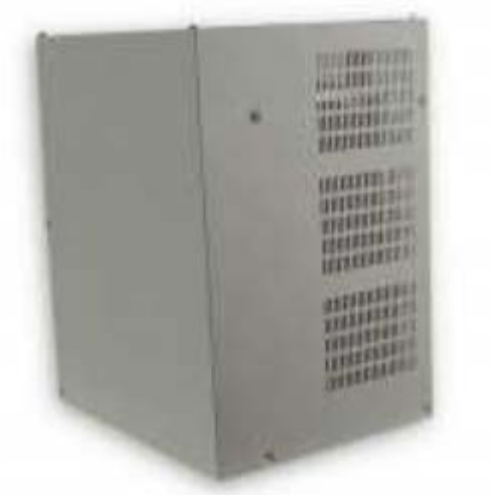


Wall Stand

<u>High Voltage X-ray generator, model SHFR</u>

The Radiographic System Challenge X is interfaced with SHFR High Voltage X-ray generator family. This High Voltage X-ray generator is already placed in the U.S. market.

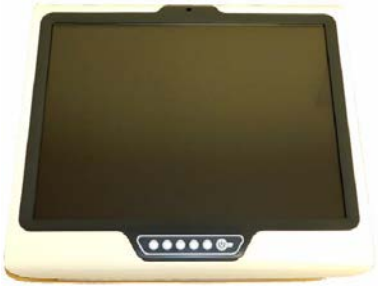
- The High Frequency X-ray generator provides all the advantages of high frequency waveform Generators, including lower patient dose, shorter exposure times and greater accuracy and consistency.
- The X-ray generator is controlled by multiple microprocessors providing increased exposure consistency, efficient operation and extended Tube life. A high level of self-diagnosis greatly increases serviceability and reduces down time.



Generator

Control Console, model STH (optional):

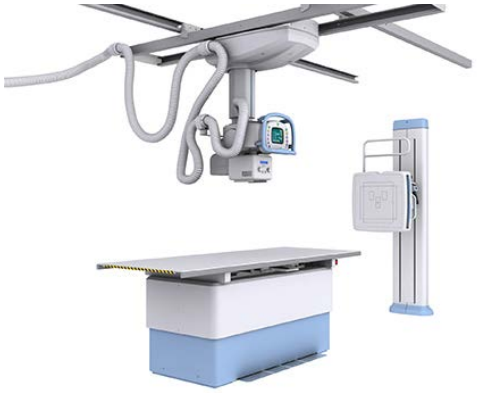
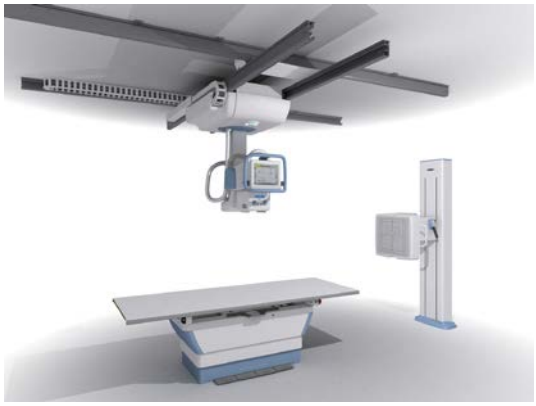
The STH Touch Screen Control Console is an optional item, which allows the operator to control and display for radiographic operations. It can replace the X-ray generator Control Console integrated in an imaging system (such as: CANON CXDI control console). It is an External Control Console of 15 inch that comprises a capacitive touch screen with an embedded PC. The console is designed to provide, and easy operation and it is the interface with the Generator and the rest of the System. (Pictured below)



Control Console (Wired)

Substantial Equivalence Chart

Characteristic	Predicate: K133782, Trade/Device Name: "NOVA FA DR System"	Radiographic System Challenge X
Indications for 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

Characteristic	Predicate: K133782, Trade/Device Name: "NOVA FA DR System"	Radiographic System Challenge X
Photo		
Digital Receptor panel	CXDI CANON Detector 401C/401G Compact (K103591). CXDI CANON Detector 55C (K091436) CXDI CANON Detector 501 C (K111682)	CXDI CANON Detector 401C / 401G Compact / (K103591). Plus: CANON CXDI-401C / 401G Wireless (K133693) CANON CXDI-701C / 701G Wireless (K131106) CANON CXDI-801C / 801G Wireless (K131106) CANON CXDI-710C Wireless (K170332) CANON CXDI-810C Wireless (K170332) CANON CXDI-410C Wireless (K171270) CANON CXDI-402C Wireless (K192632) CANON CXDI-702C Wireless (K192632)
Scintillator	CsI (TI) and GOS	SAME
Tube mount	Ceiling Suspension	SAME
Image acquisition Software	Canon control software CXDI-NE	SAME
Panel Interface	Ethernet or Wi-Fi wireless	SAME
Meets US Performance Standard	YES 21 CFR 1020.30 Diagnostic x-ray systems and their major components. 21 CFR 1020.31 Radiographic equipment.	SAME
X-ray generator	SHF Family Output power: 50 kW, 65 kW, 80 kW. kV Range: from 40 kV to 150 kV, in 1 kV steps. mA Range: from 10 mA to 1000 mA (Depends on the generator and X-ray tube model)	SHFR Family: Output power: 32 kW, 40 kW,50 kW, 65 kW, 80 kW. kV Range: SAME mA Range: SAME
Collimator	Ralco R225 ACS (Automatic Collimator) Ralco R225 (Manual Collimator)	SAME
Power Source	Mains operated.	SAME

6) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new device is as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination.

7) **Summary of non-clinical testing**: Systems covering all generator/panel combinations were assembled and tested and found to be operating properly.
Firmware was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.*
Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014*. The digital panel software employed was already reviewed by FDA in 510(k)s noted in "reference devices" above. Labeling was developed and information provided in accordance with this FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff, November 2017*. Labeling also includes reference to the Image Gently website (http://www.imagegently.org/). Because the device contains wireless technology, we consulted *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff, AUGUST 2013* and we incorporated those recommendations into our labeling.

   The Radiographic System Challenge X has been tested to be in compliance with the following International Standards:
   a) 21 CFR 1020.30 Diagnostic x-ray systems and their major components and 21 CFR 1020.31 Radiographic equipment. A product report for the new SHFR generator series was previously submitted.
   b) IEC 60601-1:2005+A1:2012 (Edition 3.1) Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance.
   c) IEC 60601-1-2:2014 (Edition 4.0) Medical electrical equipment Collateral Standard: Electromagnetic compatibility Requirements and tests.
   d) IEC 60601-1-3:2008+A1:2013 (Edition 2.1) Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
   e) IEC 60601-2-54:2009+A1:2015 (Edition 1.2) Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy.
   f) IEC 60601-2-28:2010 (Edition 2.0) IEC 60601-1-6:2010 + A1:2013 (Edition 3.1) Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
   g) IEC 62304:2006 + A1:2016 (Edition 1.1) Medical device software - Software life cycle processes

8) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence because all digital x-ray receptor panels have had previous FDA clearance.

9) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of Sedecal SA. that the new Radiographic System Challenge X are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**