Prognosys Medical Systems Private Limited
% Dr. Shruti Sancheti
Manager - Quality and Regulatory Affairs
IZiel Healthcare
14, Hadapsar Industrial Estate
Hadapsar, Pune, 411013
INDIA

January 24, 2019

Re: K183541
Trade/Device Name: ProRad 2FC and ProRad 3NC Digital Stationary Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: December 20, 2018
Received: December 21, 2018

Dear Dr.Sancheti:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K183541

Device Name

ProRad 2FC and ProRad 3NC Digital Stationary Radiographic Systems

Indications for Use *(Describe)*

ProRad Series Stationary Radiographic System is intended for use by a qualified, trained doctor or technician on both adult and paediatric 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)

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510(k) SUMMARY

510(k) summary of Safety and Effectiveness for ProRad 2FC and ProRad 3NC Stationary Radiographic Systems is provided in accordance with 21 CFR 807.92.

Date:	October 5, 2018
Submitter (Owner):	V. Krishna Prasad President Prognosys Medical Systems Pvt. Ltd. No. 249, Ground Floor, Front Building, 4th Main Road, Chamrajpet, Bangalore – 560 018, Karnataka, India Phone: +91-8026621544 E-mail Id: info@prognosysmedical.com
510(k) Contact Person:	Dr. Shruti Sancheti Manager-Quality & Regulatory Affairs IZiel Healthcare 14, Hadapsar Industrial Estate, Hadapsar, Pune – 411013 India. P: +91-72762 2555 M:+91-9518546814 Email: shruti.sancheti@izielhealthcare.com
Device Trade Name:	ProRad 2FC and ProRad 3NC Stationary Radiographic Systems
Regulation Number:	21 CFR 892.1680
Regulation Description:	Stationary X-Ray System
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	KPR, MQB
Predicate Device:	1. Jumong Series Stationary Radiographic System (K150816) 2. Amrad Medical OTS Digital Radiography System, Amrad Medical DFMTS Digital Radiography System, Amrad Medical FRS Digital Radiography System (K153119)

Indications for Use:

The ProRad Series Stationary Radiographic System is intended for use by a qualified, trained doctor or technician on both adult and paediatric 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.

Description of the Device:

The ProRad series Stationary Radiographic System is a diagnostic x-ray system intended for general purpose radiographic imaging of the human body. There are two types of configurations (2FC and 3NC) for ProRad; the difference is in the

mounting of the X-ray tube. For X-ray tube mounting the configuration is either the floor mounted (2FC) or ceiling suspension (3NC) assembly.

The devices are a new combination of a previously cleared solid state digital x-ray acquisition panel and software with the diagnostic x-ray components (including X-ray tube, high frequency X-ray generator, a tilting vertical bucky, X-ray table and collimator) required to make a complete system. The purchaser may select any of the digital panels and software based on the user's requirements. The other components are also available in different configurations to meet specific customer needs. The X-ray panel and imaging software have been previously cleared by the FDA, and most of the other components are used in previously cleared 510(k) devices (respective approval numbers are discussed in Section 11, Table 1). Details of the various configurations of all the components are given in **Table 1** below:

Table 1: Available system configurations

Component Category	Component Description and Model	Manufacturing Location	ProRad 2FC	ProRad 3NC
Digital Imaging System	CANON Flat Panel Detector CXDI-401C Compact	Canon Inc., Japan	√	√
	CANON Flat Panel Detector CXDI-410C Wireless		√	√
	CANON Portable Detector CXDI-701C Wireless		√	√
	CANON Portable Detector CXDI-710C Wireless		√	√
	VAREX PAXSCAN 4343R v3	Varian Medical Systems, Inc.	√	√
	VAREX PAXSCAN 4336W v4 Wireless		√	√
	VAREX (PerkinElmer) Flat Panel Detector XRpad 4343F MED	Perkin-Elmer, Inc	√	√
	VAREX (PerkinElmer) Flat Panel Detector XRpad 4336 MED Wireless		√	√
	DRTECH Digital Flat Panel X-ray Detector EVS 4343, EVS 4343G	DRTECH Corporation	√	√
	DRTECH Digital X-ray Detector EVS 3643, EVS 3643G Wireless		√	√
Image Acquisition Software	Canon CXDI NE	Canon Inc., Japan	√	√
	DROC (Digital Radiography Operator Console)	E-COM Technology Ltd.	√	√
	Econsole1	DRTECH Corp.	√	√

Component Category	Component Description and Model	Manufacturing Location	ProRad 2FC	ProRad 3NC
X-ray Generator	CPI CMP 200DR (32 kW, 40 kW, 50 kW, 65 kW, 80 kW)	Communications & Power Industries, Canada	√	√
X-ray Tube	TOSHIBA (E7239FX, E7242FX, E7252X, E7254X, E7869X, E7884X, E7843X)	TOSHIBA ELECTRON TUBES & DEVICES CO., LTD.	√	√
	VAREX (RAD14, RAD60, RAD92)	Varian Medical Systems, Inc.	√	√
Collimator	Ralco (R221, R225ACS)	Ralco Italy	√	√
	Daesung (M38)	Daesung Corporation, Korea	√	√
Mechanical Tube Stand	Ceiling Mounted Tube Stand - Full Auto- Single (SCS-FA) - Auto Tracking- Single (SCS-AT) - Manual- Single (SCS-MA) - Full Auto- Dual (DCS-FA) - Auto Tracking- Dual (DCS-AT) - Manual- Dual (DCS-MA)		--	√
	Floor Mounted Tube Stand - Full Auto- Single (SFT-FA) - Auto Tracking- Single (SFT-AT) - Manual- Single (SFT-MA) - Auto Tracking (FTC-AT) - Manual (FTC-MA) - Full Auto- Dual (DFT-FA) - Auto Tracking- Dual (DFT-AT) - Manual- Dual (DFT-MA)		√	--
Mechanical Bucky Stand	Floor Mounted Vertical Bucky Stand - VB-MO - VB-MA - VBNTL-MO - VBNTL-MA		√	√
Patient Table	- Mobile Patient Table PRO-MT - Mobile Patient Table with 4-way movement PRO-MT4 - Mobile Patient Table with 6-way movement PRO-MT6 - Fixed Patient Table PRO-FT - Fixed Patient Table with 4-way movement PRO-FT4 - Fixed Patient Table with 6-way movement PRO-FT6		√	√

Safety and effectiveness, comparison to predicate device:
This combination device has the same indications for use, is similar in technological characteristics to the predicate devices and employs already 510(k) cleared digital panels and software. In addition, most of the other components employed in the device have already been used in previously cleared 510(k) devices. The device has also been adequately tested to the relevant performance standards to prove that the integrated device is safe and effective for the intended use.

Substantial equivalence:

Comparable Properties	Subject Device	Predicate Device 1 (K150816)	Predicate Device 2 (K153119)	Comparison Results
Intended Use	ProRad Series Stationary Radiographic System is intended for use by a qualified, trained doctor or technician on both adult and paediatric 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.	Jumong Series 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.	These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.	Equivalent

Comparable Properties	Subject Device	Predicate Device 1 (K150816)	Predicate Device 2 (K153119)	Comparison Results
Configuration of Digital Panels	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	Same
Digital Panel Models and their Clearance Numbers	- CANON Flat Panel detector CXDI-401C Compact (K103591) - CANON Flat Panel detector CXDI-410C Wireless (K171270) - CANON Portable detector CXDI-701C Wireless (K131106) - CANON Portable detector CXDI-710C Wireless (K170332) - VAREX PAXSCAN 4343R v3 (K172951) - VAREX PAXSCAN 4336W v4 (K161459) - VAREX (PerkinElmer) XRpad 4343F MED Flat Panel Detector (K142698) - VAREX (PerkinElmer) XRpad 4336 MED Flat Panel Detector (K140551) - DRTECH EVS 4343, EVS 4343G Digital Flat Panel X-ray Detector (K162555) - DRTECH EVS 3643, EVS 3643G Digital X-ray detector (K162552)	Vieworks - Vivix-S Wireless (K122865) - Vivix-S with Vxvue (K122866) - Vivix-S (K120020)	- VAREX PAXSCAN 4343R (K130318) - VAREX PAXSCAN 4336R (K130318)	Similar functionality (Note 1)
Image Acquisition Panel Specifications	- 3,320 x 3,408 Pixels 125 µm (CXDI 401C Compact) - 3,320 x 3,408 Pixels 125 µm (CXDI 410C Compact) - 2,800 x 3,408 Pixels 125 µm (CXDI 701C)	- FXRD-1717SA, FXRD-1717SB) 3,072 x 3,072, 140µm or - FXRD-1417SA,	- 3,072 x 3,072 Pixels 139 µm (PAXSCAN 4343R) - 2,560 x 3,072 Pixels 139 µm	Similar functionality (Note 1)

Comparable Properties	Subject Device	Predicate Device 1 (K150816)	Predicate Device 2 (K153119)	Comparison Results
	- 2,800 x 3,408 Pixels 125 µm (CXDI 710C) - 3,072 x 3,072 Pixels 139 µm (PAXSCAN 4343R v3) - 3,072 x 2,560 Pixels 139 µm (PAXSCAN 4336W v4) - 4,318 × 4,320 Pixels 100 µm (XRpad 4343F) - 3,556 × 4,320 Pixels 100 µm (XRpad 4336) - 3,072 x 3,072 Pixels 140 µm (EVS 4343, EVS 4343G) - 2,560 x 3,072 Pixels 140 µm (EVS 3643, EVS 3643G)	FXRD-1417SB) 2,560 x 3,072, 140µm - Wireless: FXRD-1417WA, FXRD1417 WB, 2,560 x 3,072, 140µm	(PAXSCAN 4336R)	
DICOM	DICOM 3	DICOM 3	DICOM 3	Same
WiFi Wireless IEEE802.11n (All others are Ethernet Tethered.)	- CANON CXDI 701C Wireless - VAREX PAXSCAN 4336W v4 - PerkinElmer XRpad 4336 MED Flat Panel Detector - DRTECH EVS 3643, EVS 3643G Digital X-ray detector	K122865 Vivix-S Wireless	Wireless detector- Not applicable	Similar functionality
Image Acquisition Software	- CANON CXDI NE (K153312, K171270) - DROC (Digital Radiography Operator Console) (K130883) - Econsole1 (K152172)	- Vieworks Vivix-S With Vxvue (K122866) - Vivix-S (K120020)	ECOM Software (K130883)	Similar functionality (Note 2)
Power Source	AC Line, various voltages available	AC Line, various voltages available	AC Line	Same
X-ray Generator	CPI CMP 200DR (32 kW, 40 kW, 50 kW, 65 kW, 80 kW) (125 kV/150 kV for 32 kW, 40 kW) (150kV for 50 kW, 65 kW, 80 kW)	CPI CMP200DR	CPI CMP 200DR HF, 150kV (40kW, 50kW, 65 kW, 80 kW)	Same or similar functionality (Note 3)

Comparable Properties	Subject Device	Predicate Device 1 (K150816)	Predicate Device 2 (K153119)	Comparison Results
			CPI CMP 200DR HF, 125kV (40kW)	
X-ray Tubes	TOSHIBA E7239FX: 125kV, LF2.0, SF1.0, 140kHU E7242FX: 125kV, LF1.5, SF0.6, 200kHU E7252X: 150kV, LF1.2, SF0.6, 300kHU E7254X: 150kV, LF1.2, SF0.6, 400kHU E7869X: 150kV, LF1.2, SF0.6, 600kHU E7884X: 150kV, LF1.2, SF0.6, 300kHU E7843X: 150kV, LF1.2, SF0.6,150kHU VAREX RAD14: 150kV, LF1.2, SF0.6, 300kHU RAD60: 150kV, LF1.2, SF0.6, 400kHU RAD92: 150kV, LF1.2, SF0.6, 600kHU	--	150 kVp 0.6/1.2 mm focal spots	Similar functionality (Note 4)
Collimator	- Ralco R221, R225ACS - Deasung M38	Ralco R225	Collimare	Similar functionality (Note 5)
Performance Standard	FDA 21 CFR 1020.30-31	FDA 21 CFR 1020.30-31	FDA 21 CFR 1020.30-31	Same
Electrical Safety	Electrical Safety as per IEC 60601.	Electrical Safety as per IEC 60601.	Electrical Safety as per IEC 60601.	Same

Note	Description
Note 1	The subject device utilizes a different X-Ray flat panel detector; however, the flat panel detectors used by the subject device are already previously cleared by the FDA and the testing demonstrate that it does not raise the level of safety concern and affect any effectiveness. The relevant 510(k) approval numbers are K103591, K171270, K131106, K170332, K172951, K161459, K142698, K140551, K162555 and K162552.

Note 2	Prognosys utilizes image processing software that has been previously cleared by the FDA. The respective 510(k) approval numbers are K153312, K171270, K130883 and K152172. Prognosys does not modify any software utilized for image processing or display.
Note 3	In addition to the various power ratings of x-ray generators used by predicate device, the subject device also utilizes a similar X-ray generator with different power ratings which does not raise any level of safety concern and affect any effectiveness; the generator frequency does affect the X-ray exposure parameters. In addition, the X-ray generators used by the subject device have also been used in previously cleared 510(k) devices with approval numbers K150816 and K153119.
Note 4	Both configurations (Toshiba and Varex) provide similar imaging resolution on both focal spots. In addition, the X-ray tubes have been used in previously cleared 510(k) devices with approval numbers K152767, K173823, K103050 and K1881874.
Note 5	The inherent filtration for the collimator in the subject device is different from the predicate device; this difference does not affect the safety and effectiveness.

The ProRad series Stationary Radiographic System is a diagnostic x-ray system intended for general purpose radiographic imaging of the human body. This device utilizes previously cleared X-ray flat panel detectors and image processing software which are the main components of any X-Ray diagnostic system. The other components of the imaging system such as the X-Ray generator and X-Ray Tube are used in previously cleared 510(k) devices and are either identical or similar to the predicate devices. The remaining other components such as the Collimator, Mechanical Tube Stand, Mechanical Bucky Stand and Patient Table have no impact on the safety and effectiveness of the system. In addition, the subject device has been tested to the relevant performance standards as summarized below.

Summary of non-clinical testing:

The ProRad 2FC and ProRad 3NC Digital Stationary Radiographic Systems comply with the following standards:

- IEC 60601-1: 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 Collateral standard: Electromagnetic compatibility requirements and tests

- IEC 60601-1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 14971: Medical devices. Application of risk management to medical devices

Furthermore, cybersecurity concerns were addressed based on the US FDA Guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 2014" in the device labeling of these products.

Summary of clinical testing:
Since the digital x-ray panels and software have previously received FDA clearance, a clinical study was not required as per the FDA guidance document. The following information was not necessary to demonstrate substantial equivalence but provides additional support that the device works as intended. Clinical images acquired by the device were reviewed by a radiologist. The images were found to be acceptable and allowed the radiologist to make an accurate diagnosis.

Conclusion:
Technological differences from the predicate devices include different detectors, some with wireless functionality, different collimators and x-ray tubes. Although some of the components differ from the predicate devices, the detectors and other components have been cleared as part of other 510(k) submissions. Despite the few differences, after analysis of all test information, including the indications for use and test data, it can be concluded that the devices "ProRad 2FC and ProRad 3NC Stationary Radiographic Systems" are as safe and effective as the predicate devices, thus rendering them substantially equivalent to the predicate devices.