January 11, 2024

Philips Medical Systems DMC GmbH
℅ Ming Xiao
Regulatory Affairs Manager
Roentgenstrasse 24
Hamburg, Hamburg 22335
GERMANY

Re: K233945
Trade/Device Name: ProxiDiagnost N90 / Precision CRF (706110, 706400)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, KPR
Dated: December 14, 2023
Received: December 14, 2023

Dear Ming Xiao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233945

Device Name

ProxiDiagnost N90 / Precision CRF (706110, 706400)

Indications for Use *(Describe)*

ProxiDiagnost N90 / Precision CRF is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding 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.

510(k) Summary of Safety and Effectiveness K233945

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

Preparation Date:	December 14th, 2023
510(k) Owner:	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg, GERMANY Establishment registration number: 3003768251
Primary Contact:	Ming Xiao Regulatory Affairs Manager Diagnostic X-Ray (DXR) Phone: +49(40) 34971-2306 E-mail: ming.xiao@philips.com
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Proposed Device	
Device Name	ProxiDiagnost N90 / Precision CRF (706110, 706400)
Legal Manufacturer	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg, GERMANY
Classification Name:	Image-intensified Fluoroscopic X-ray System
Classification Regulation:	21 CFR Part 892.1650
Classification Panel:	90 – Radiology
Device Class:	Class II
Classification Product Code:	JAA
Subsequent Product Code:	KPR
Predicate Device	
Device Name	ProxiDiagnost N90 (K212837, September 21, 2021)
Legal Manufacturer	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg, GERMANY
Classification Name:	Image-intensified Fluoroscopic X-ray System
Classification Regulation:	21 CFR Part 892.1650
Classification Panel:	90 – Radiology
Device Class:	Class II
Classification Product Code:	JAA
Subsequent Product Code:	KPR

Device Description

Same as the legally marketed predicate device ProxiDiagnost N90 (K212837, Substantial Equivalent (SE) date on September 21, 2021), the proposed ***ProxiDiagnost N90 / Precision CRF*** is a multi-functional general Radiography/ Fluoroscopy (R/F) system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

Same as the legally marketed predicate device ProxiDiagnost N90 (K212837, SE date on September 21, 2021), the proposed ***ProxiDiagnost N90 / Precision CRF*** is a nearby controlled fluoroscopy system in combination with high-end digital radiography system consisting of a floor-mounted tilt adjustable patient support table and a scan unit consisting of a tube and a flat panel dynamic detector, Pixium FE4343F, for the fluoroscopy examinations. The tabletop can be moved by a motor in the lateral and longitudinal direction and can be tilted at -85° to +90° degrees. The scan unit tilts with the table and can be moved in the longitudinal and lateral direction, relative to the table and to the patient. The system is suitable for routine X-ray examinations and fluoroscopy examinations on patients in standing, seated, or lying positions. Same as the legally marketed predicate device ProxiDiagnost N90 (K212837, SE date on September 21, 2021), the proposed ***ProxiDiagnost N90 / Precision CRF*** retrieves images by means of a Cesium Iodide flat panel detector.

Same as the legally marketed predicate device ProxiDiagnost N90 (K212837, SE date on September 21, 2021), the proposed ***ProxiDiagnost N90 / Precision CRF*** consists of the Basic unit ("geometry" or "table unit"), Workstation Eleva Workspot (with integrated generator control, hand switch, keyboard, mouse, touch screen and PC), dual screen-monitor, Spot film device (digital camera or flat panel detector), Fixed Detector (Fluoroscopy), X-ray Generator for R/F applications, X-ray tube assembly. The optional components like wireless portable detectors small and large, Bucky tray for wireless portable detectors SkyPlate detector, Ceiling Suspension, Fixed Vertical stand, Ceiling Suspension for monitors, monitor trolley, Remote control for R/F (Radiography-fluoroscopy) viewer, accessories for "Stitching Stand", are also available.

Same as the legally marketed predicate device ProxiDiagnost N90 (K212837, SE date on September 21, 2021), the Eleva software of the proposed ***ProxiDiagnost N90 / Precision CRF*** is based on a workstation i.e., Eleva Workspot (computer, keyboard, display, and mouse) that is used by an operator to preset examination data and to generate, process and handle digital x-ray images. The Eleva Software system is decomposed into software components. These components are clustered in three component collections like the image handling focused Back-end (BE), the acquisition focused Front-end (FE) and Image Processing (IP). The Eleva software is intended to acquire, process, store, display and export digital fluoroscopy and radiographic images.

The accessories for the proposed ***ProxiDiagnost N90 / Precision CRF*** are the same as the predicate device ProxiDiagnost N90 (K212837).
The list of the accessories for the proposed ***ProxiDiagnost N90 / Precision CRF***:

- Footrest
- Hand Grips

Radiation Protection Accessories

- Flexible Radiation Protection Apron

- Front Radiation Protection Apron

Additional Accessories (Optional)

- Monitor Trolley
- Monitor Ceiling Suspension
- Parking Frame for Accessories
- Shoulder Support
- Side bar
- Compression Belt
- Adjustable Lateral Cassette Holder
- Leg Supports
- Infusion Bottle Holder
- Arm Support for Catheterization
- Ankle Clamps
- Overhead Hand Grip
- Adult Headrest
- Mattress
- Rotatable Stool for Footrest
- Pediatric Micturition Set
- Stretch Grip for Wall Stand
- Bar Code Scanner
- Patient Support
- Stitching Ruler

Accessories for the SkyPlate Detector (Optional)

- Mobile Detector Holder
- Detector Holder Patient Bed
- Portable Panel Protector
- Detector Handle
- WPD Bags
- Grids for SkyPlate Detector large

The Components for the proposed ***ProxiDiagnost N90 / Precision CRF*** are the same as the predicate device ProxiDiagnost N90 (K212837).

The list of the Components for the proposed ***ProxiDiagnost N90 / Precision CRF***:

- Eleva Workspot and RF Viewer
- UPS for Eleva Workspot (Optional)
- Table
- Indication Box
- Foot Switch
- Ceiling Suspension Motorized CSM3 (Optional)
- Wall Stand (Vertical Stand VS2) (Optional)
- SkyPlate / Portable Detector (Optional)

The proposed device complies to '*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*, dated September 1, 2016'. The solid-state imaging components including the detector in the proposed device have the same physical, functional, and operational characteristics as the predicate device (K212837). Also, other image chain components like X-ray tube and generator, which are used for exposure characteristics and clinical performance evaluation remains the same. Hence all the features and characteristics potentially influencing

image quality of the proposed are in accordance with FDA guidance document. Additionally, image quality testing has been performed on the proposed device for the changes that are affecting the image quality.

Indication for Use:
ProxiDiagnost N90 / Precision CRF is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.

Comparison to Predicate Device / Design Changes Summary:
The proposed ***ProxiDiagnost N90 / Precision CRF*** uses the same workflow as the predicate device ProxiDiangost N90 (K212837) with only the following modifications. Differences on the proposed device with respect to the predicate device ProxiDiagnost N90 (K212837) are as follows:

1) **Change #1: Modifications to System Software Baseline upgrade releases for ProxiDiagnost N90**
    a) Release Version R1.1.0 was internally released only, never released for production, based on predicate device ProxiDiagnost N90 (K212837)
    b) Release Version R1.1.1 was released based on design changes on Software updates
    c) Release Version R1.1.2 was aborted
    d) Release Version R1.1.3 is for proposed device ***ProxiDiagnost N90*** per current submission

The modifications have no impacts on product safety, Intended Use, effectiveness, functionality and performance.

2) **Change #2: Modifications to Ceiling Suspension Motorized (CSM/CSM3)**
This is an optional component for radiography examinations only.
    a) Replacing the Beta rotation lock mechanism parts
    b) Introduction of dual sourcing for CSM/CSM3 Tube mounts
    c) Improvements for Metallic Flakes CS Telescopic End Cover Kit

The modifications have no impacts on product safety, Intended Use, effectiveness, functionality and performance.

3) **Change #3: Modifications to Wall Stand (VS2)**
    a) Replacing the Adapter parts for Bucky Unit 2
    b) Update VS2 combined family label
    c) VS2 Firmware change from FW 10.01.09 to FW 10.01.10 Version

The modifications have no impacts on product safety, Intended Use, effectiveness, functionality and performance.

4) **Change #4: Modifications to Patient Table**
    a) Improvement on cable sleeve material
    b) Replacing SGCU PCBA parts
    c) Improvement on under table Collimator
    d) Changes in the M shield
    e) Replacing the Emergency stop switch

The modifications have no impacts on product safety, Intended Use, effectiveness, functionality and performance.

5) Change #5: Modification to Monitor ceiling suspensions (MCS)

a) Introduction of Ceiling Connection Box for MCS

The modification has no impacts on product safety, Intended Use, effectiveness, functionality and performance.

6) Change #6: Modifications to accessory and components

a) Replacing the Motor Gear Drive
b) Replacing the Microcontroller IC for Bucky Unit family
c) Replacing the Power Supply boards PCBAs

The modifications have no impacts on product safety, Intended Use, effectiveness, functionality and performance.

7) Change #7: Serviceability features: Introduction of Service parts for PC AWS-DI

The change has no impacts on product safety, Intended Use, effectiveness, functionality and performance.

8) Change #8: Modification to subsystem detector Pixium 4343RCE2

This change was necessitated by the supplier's discontinuation of the detector model Pixium 4343RCE used in predicate device ProxiDiagnost N90 (K212837). The key parameters like pixel size, pixel array, scintillator and readout mechanism remain unchanged.
The change has no impacts on product safety, Intended Use, effectiveness, functionality and performance.

9) Change #9: Software Package 1.0.1 for Precision CRF

The change has no impacts on product safety, Intended Use, effectiveness, functionality and performance.

Fundamental Scientific Technology:

The proposed ***ProxiDiagnost N90 / Precision CRF*** is substantially equivalent to the manufacturer's legally marketed devices:

- Predicate Device: ProxiDiagnost N90, (K212837, SE date September 21, 2021), Philips Medical Systems DMC GmbH

A detailed comparison of the proposed and predicate device (K212837) is provided in **Table 1**.

Design control activities for each change identified along with associated verification, validation, and risk mitigation activities performed to ensure that the proposed modifications do not affect device safety and / or effectiveness.

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	**Proposed Device, ProxiDiagnost N90 / Precision CRF**
Legal Manufacturer	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg Germany	Identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	**Proposed Device, ProxiDiagnost N90 / Precision CRF**
Classification	Class II per 21 CFR Part 892.1650, Primary Product code: JAA Secondary Product code: KPR	Identical
Regulation Name	Stationary x-ray system	Identical
Class	II	Identical
Review Panel	Radiology	Identical
Indications for Use	ProxiDiagnost N90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.	Identical ProxiDiagnost N90 / Precision CRF is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography. Equivalent; No impact to safety and effectiveness of the device.
Energy Source	X-ray	Identical Equivalent; No impact to safety and effectiveness of the device.
Principle of Operation	ProxiDiagnost N90 systems are intended for the medical application procedures for fluoroscopy and Radiography. ProxiDiagnost N90 systems allow radiography (with optional 2nd Tube on Ceiling suspension) and fluoroscopy on a patient in supine, seated or standing position, depending on the specific indication. Depending on the specific indication, X-ray procedures vary in patient positioning and the modification of radiographic parameters	Identical Equivalent; No impact to safety and effectiveness of the device.
Table Features		
Working height (tabletop center to floorplate)	833 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Table tilt movement	+90° to -85° Speed of tilt < 1°/s to 6°/s	Identical Equivalent; No impact to safety and effectiveness of the device.
Tabletop suspension	Two sides suspensions	Identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
		Equivalent; No impact to safety and effectiveness of the device.
Tabletop material	Sandwich of laminate, carbon, and foam	Identical Equivalent; No impact to safety and effectiveness of the device.
Tabletop movement	Transversal–100 mm to +90 mm Longitudinal: Maximum ±835 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Tabletop absorption	0.6mm Al typical @ 100kV	Identical Equivalent; No impact to safety and effectiveness of the device.
Maximum patient weight	static: 300 kg tilt: 250 kg all movements: 185 kg	Identical Equivalent; No impact to safety and effectiveness of the device.
Lateral scan distance	220 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Lateral scan speed	Manual Movement	Identical Equivalent; No impact to safety and effectiveness of the device.
Longitudinal scan distance	750 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Source image distance	810 mm to 1,300 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Other Components		
Generator	Philips Velara GCF/RF, 65 kW, optional 80 kW	Identical for ProxiDiagnost N90 For Precision CRF, only 80 kW is applicable. Equivalent; No impact to safety and effectiveness of the device.
Tube	Philips SRM 2250 ROTGS 504 or SRO 2550 ROT380	Identical Equivalent; No impact to safety and effectiveness of the device.
Fixed Detector (Fluoroscopy)	Pixium FE 4343F	Identical Equivalent; No impact to safety and effectiveness of the device.
Modulation Transfer Function (MTF) (according to IEC 62220-1-3 standard)	lp/mm % 1 66 2 35 3 19 3.4 15	Identical Equivalent; No impact to safety and effectiveness of the device.
Detective Quantum Efficiency (DQE)	DQE at 1 µGy lp/mm %	Identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
(according to IEC 62220-1-3 standard)	0.05 65 1 51 2 41 3 27 3.4 18	Equivalent; No impact to safety and effectiveness of the device.
System Control	Nearby	Identical Equivalent; No impact to safety and effectiveness of the device.
Collimator (Fluoroscopy)	Rectangular collimation	Identical Equivalent; No impact to safety and effectiveness of the device.
Grid	Parkable	Identical Equivalent; No impact to safety and effectiveness of the device.
Picture archiving and communication system	Available	Identical Equivalent; No impact to safety and effectiveness of the device.
Extended reviewing options		
Remote Control	Infrared remote control for Image Navigation	Identical Equivalent; No impact to safety and effectiveness of the device.
Reference monitor (Optional)	Additional monitor for reference image support [Change #1b] is available. The additional reference monitor is made available for the display of a reference image in the Examination Room and optionally in Control Room.	Identical Equivalent; No impact to safety and effectiveness of the device.
Image processing		
Image processing functionality		
DSA (Digital Subtraction Angiography) (Optional)	Digital Subtraction Angiography functionality is available. It is used for angiography and provides interactive viewing operations on a vascular run, so that the vascular anatomy becomes visible.	Identical Equivalent; No impact to safety and effectiveness of the device.
Predefined annotations integrated into the dynamic viewer	Predefined annotations are available which enables the user to assign annotation to the image with the help of a set of predefined annotations. This speeds the user workflow.	Identical Equivalent; No impact to safety and effectiveness of the device.
Image processing functionality		
Bone Suppression (Optional)	Bone Suppression post-processing application is available. It is intended to generate secondary digital radiographic	Identical for ProxiDiagnost N90 Bone suppression is not applicable for Precision CRF

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
	image of the chest by suppressing bones from the original image.	Equivalent; No impact to safety and effectiveness of the device.
UNIQUE	• Dynamic UNIQUE (fluoroscopy modality only)- no change • UNIQUE 2 (radiography modality only)	Identical Equivalent; No impact to safety and effectiveness of the device.
Intuitive User Interface for Processing Parameters	An intuitive way of modifying the available parameters is introduced (e.g., contrast, brightness, noise limit, detail enhancement etc.) on the Eleva user interface.	Identical Equivalent; No impact to safety and effectiveness of the device.
Deviation and Target Exposure Indices	Deviation Index (DI) function is available to quantify the deviation of the Exposure Index (EI_s) from the Target Exposure Index (EI_T). This feature is used by the clinical user only to identify whether a certain image has been correctly exposed.	Identical Equivalent; No impact to safety and effectiveness of the device.
SkyFlow (Optional)	Skyflow is extended to imaging of other anatomies (e.g., Leg, hand etc.) including the chest AP/PA imaging, with Skyplate detector.	Identical for ProxiDiagnost N90 SkyFlow is not applicable for Precision CRF. Equivalent; No impact to safety and effectiveness of the device.
Access to and Export of Original Image Data	Access to and Export of Original Image Data feature enables the access to an export of original image data (clean raw images without any modification) on the system.	Identical Equivalent; No impact to safety and effectiveness of the device.
One Button Stores All (OBSA): Content and performance Improvement	System can additionally use OBSA for sending logfile (Alert files) to central database (RSN, e.g., RADAR or M2M server) frequently by single button click.	Identical Equivalent; No impact to safety and effectiveness of the device.
View Selection for Changed X-Ray Generation Data Sets	Users can change a data set only for current examination or the examinations that are using this data set. In addition to the current examinations, the user can select to apply the changes to subset of all examinations too that are using this data set.	Identical Equivalent; No impact to safety and effectiveness of the device.
Avoid Ghosting in Verification Images of Portable Detectors	The feature to avoid ghosting in verification images of portable detectors is available. It enables the system to display verification images on wireless (SkyPlate) detector without ghosting artifacts	Identical Equivalent; No impact to safety and effectiveness of the device.

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
Software		
Operating System	Windows 10	Identical Equivalent; No impact to safety and effectiveness of the device.
Image Chain (fluoroscopy)	Philips Dynamic Eleva Image Chain	Identical Equivalent; No impact to safety and effectiveness of the device.
Image acquisition	Eleva Workspot (Increment 42)	Identical Eleva Workspot (Increment 42.3) is applicable for ProxiDiagnost N90. Eleva Workspot (Increment 42.2) is applicable for Precision CRF. Equivalent; No impact to safety and effectiveness of the device.
Ceiling Suspension (optional) for Radiography examinations only		
Type	Four-part aluminum telescopic column with spring counter balanced holder for X-ray tube assembly; adaptable to individual room heights	Identical Equivalent; No impact to safety and effectiveness of the device.
Movement	3440 mm to 6140 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Transverse travel	1500 mm to 3220 mm	Identical Equivalent; No impact to safety and effectiveness of the device.
Vertical travel	1650mm to 1705mm	Identical Equivalent; No impact to safety and effectiveness of the device.
X-ray tube assembly rotation	• around vertical axis: ±180°, lock-in position every 45° • around horizontal axis: ±115°, lock-in position at 0°, ±90°	Identical Equivalent; No impact to safety and effectiveness of the device.
Tube Head control	• Tube head operation user interface: The User interface on Eleva tube head is touch control. • Display: 12” color graphics display with touch control functionality for tube head operation. Eleva screen display in the examination room enables the user to use all the control room parameters from examination room as well.	Identical Equivalent; No impact to safety and effectiveness of the device.

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
	• Control Handle: Control handle with flat capacitive sensor for releasing brakes for the ceiling suspension movement.	
Collimator	• Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible • With light field indicator • Live Camera (optional) on tube head for patient positioning support • With 2 Lasers (inside the collimator) • Detector Calibration with a Filter integrated into the Collimator	Identical Equivalent; No impact to safety and effectiveness of the device.
Fixed vertical stand (Optional)	• Hardware-Counterbalanced rugged column for motorized and manual vertical movement of the detector, • Vertical travel - 30 cm to 180 cm • Installation-Floor and wall attachment or floor only	Identical Equivalent; No impact to safety and effectiveness of the device.
Fixed Detector (Optional) in vertical stand (Radiography)	Pixium 4343RCE	Pixium 4343RCE2 This change was necessitated by the supplier's discontinuation of the detector model Pixium 4343RCE used in predicate device ProxiDiagnost N90 (K212837). The key parameters like pixel size, pixel array, scintillator and readout mechanism remain unchanged. Equivalent; No impact to safety and effectiveness of the device.
Wireless detector (Optional) in vertical stand and table bucky (Radiography)	• SkyPlate Large (Pixium 3543EZ) • SkyPlate Small (Pixium 2430EZ)	Identical for ProxiDiagnost N90 Only SkyPlate Large (Pixium 3543EZ) is applicable for Precision CRF. Equivalent; No impact to safety and effectiveness of the device.
SkyPlate Detector Sharing	Yes	Identical Equivalent; No impact to safety and effectiveness of the device.
Tube	High power X-ray Tube, Philips SRO 33100	Identical Equivalent; No impact to safety and effectiveness of the device.
Automatic Image Stitching (Optional)	Yes	Identical Equivalent; No impact to safety and effectiveness of the device.

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K212837)

	Predicate Device, ProxiDiagnost N90 (K212837)	Proposed Device, ProxiDiagnost N90 / Precision CRF
Service Features		
Monitoring and Firmware Updates for Field Service		
Firmware for the dynamic detector	This service tool provides functionality to perform firmware updates of the detector.	Identical Equivalent; No impact to safety and effectiveness of the device.
Monitoring of system key parameters	Service logs contain system parameters that can be monitored on the system for both the predicate device and the proposed device. However, in the proposed device, a provision is made to allow service personnel to extract logs of defined key system parameters for offline analysis too.	Identical Equivalent; No impact to safety and effectiveness of the device.
Remote access for the field service		
Additional DICOM Information to Support Performance Bridge	Additional DICOM information is collected by the Performance Bridge Data collector for logs generation.	Identical Equivalent; No impact to safety and effectiveness of the device.
Remote Silent Logfile Export	It is provided to remotely export the log files for offline analysis of the service engineers.	Identical Equivalent; No impact to safety and effectiveness of the device.
Configurable Philips Remote Server Upload	This feature is enabled with the activation of remote silent logfile export refer. In this feature, the automatic upload of the log file is configured to the Philips Remote service Server.	Identical Equivalent; No impact to safety and effectiveness of the device.

The outcome of this technological characteristics comparison and risk assessment demonstrate that the minor differences in the technological characteristics do not affect the safety or effectiveness of the proposed ***ProxiDiagnost N90 / Precision CRF***, when compared to the legally marketed predicate device ProxiDiagnost N90 (K212837). This thus demonstrates the substantial equivalence of the proposed device ***ProxiDiagnost N90 / Precision CRF*** with the predicate device ProxiDiagnost N90 (K212837).

Summary of Non-Clinical and Clinical Performance Data:

These 510(K) premarket notifications includes non-clinical performance testing. Tests were performed on the proposed ***ProxiDiagnost N90 / Precision CRF*** according to the following FDA recognized standards and guidance documents:

The verification and validation methods (test methods and acceptance criteria) used to evaluate the proposed ***ProxiDiagnost N90 / Precision CRF*** are the same as those used for the predicate device (K212837) and follow FDA-recognized consensus standards and guidance documents applicable to this device type:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Recognition #19-4)
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

disturbances - Requirements and tests (Recognition #19-8)

- IEC 60601-1-3 Edition 2.1 2013-04, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (Recognition # 12-269)
- IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability (Recognition # 5-89)
- IEC 60601-2-54 Edition 1.2 2018-06, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Recognition # 12-317)
- IEC 62304 Edition 1.1 2015-06, Medical device software - Software life cycle processes (Recognition # 13-79)
- ANSI AAMI ISO 14971: 2007/(R)2010, Medical devices-Application of risk management to medical devices (Recognition # 5-125)
- ISO 10993-1, Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Recognition # 2-258)
- IEC 62366-1 Edition 1.1 2020-06 Consolidated Version, Medical devices - Part 1: Application of usability engineering to medical devices (Recognition #5-129)
- IEC 60601-2-28 Edition 3.0 2017-06, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (Recognition #12-309)
- IEC 62220-1-3 Edition 1.0 2008-06, Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging (Recognition 12-214)
- *Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices, issued September 1, 2016*
- *Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 2017*
- *Guidance for Radio Frequency Wireless Technology in Medical Devices, issued August 14, 2013*
- *Guidance for Management of Cybersecurity in Medical Devices, issued October 2, 2014*
- *Content of Premarket Submissions for Device Software Functions Guidance,14 June 2023*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2014*
- *Off-The-Shelf (OTS) Software Use in Medical Devices, August 11, 2023*
- *Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 14, 2005*
- *General Principles of Software Validation, January 11, 2002*
- *Guidance for Management of Cybersecurity in Medical Devices, issued October 2, 2014*
- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023*

The proposed device ***ProxiDiagnost N90 / Precision CRF*** complies with the *Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*. The solid-state imaging components including the detector in the proposed device have the same physical, functional, and operational characteristics as the predicate device (K212837). Also, other image chain components like X-ray tube and generator, which are used for exposure characteristics and clinical performance evaluation remain the same. Hence, all the features and characteristics potentially influencing image quality of the proposed are in accordance with FDA guidance

document '*Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices*, dated September 1, 2016'. Additionally, Image quality testing has been performed on the proposed device for the changes that are affecting the image quality.

The proposed device ***ProxiDiagnost N90 / Precision CRF*** complies with the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005*. The changes to the proposed device do not alter the intended use or the fundamental scientific technology when compared to the predicate device (K212837). The software for the proposed device ***ProxiDiagnost N90 / Precision CRF*** has the same 'Level of concern (Moderate)' as that of the predicate device (K212837). The software verification testing has been conducted as per the level of concern.

The proposed device ***ProxiDiagnost N90 / Precision CRF*** complies with the Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 2017. The changes made to the proposed device do not affect the pediatric application. The indication for use of the proposed device is the same as the predicate device (K212837).

The proposed device ***ProxiDiagnost N90 / Precision CRF*** complies with *Guidance for Radio Frequency Wireless Technology in Medical Devices, issued August 14, 2013.* All the radiofrequency components of the predicate device (K212837) and proposed device are the same except for the replacement of Bluetooth remote control in the predicate device by infrared remote control in the proposed device. The verification testing has been conducted for the safety and efficacy of the remote control.

The proposed device ***ProxiDiagnost N90 / Precision CRF*** complies with the Guidance for Management of Cybersecurity in Medical Devices, issued October 2, 2014. A set of cybersecurity controls to assure proposed device's cybersecurity and maintain medical device functionality and safety are in place. Cybersecurity plan and risk document are prepared to assess the proposed device for the following:

- Identification of assets, threats, and vulnerabilities;
- Assessment of the impact of threats and vulnerabilities on device functionality and end users/patients;
- Assessment of the likelihood of a threat and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk.

Table 2 for the non-clinical testing that were performed on the proposed device with respect to the changes. Test results demonstrate that the proposed ***ProxiDiagnost N90 / Precision CRF*** meets acceptance criteria and is adequate for its intended use. Risk assessment activities show that the risks are sufficiently mitigated.

Table 2 Testing performed on the Proposed device

Tests	Document number	Test results
System Verification testing	• System Verification Report	Pass System verification test activities substantiate that the system conforms to the system requirements

Software verification testing	• Software Verification Report • SBOM	Pass Software verification test activities substantiate that the software conforms to the requirements
Risk control	• System Risk Matrix Status Report • System Risk Management Report • Software Risk Matrix Status Report • Software Risk Management Report	Pass System meets the defined risk control measures
Cybersecurity testing	• Cyber Security Management Plan • Cyber Security Risk Management summary • Product security vulnerability analysis report • Manufacturer Disclosure Statement for Medical Device Security	Pass Results demonstrate that the test complies with the Cybersecurity requirements

There is no clinical data submitted in this 510(k) premarket notification.

Substantial Equivalence Conclusion:
The proposed device ***ProxiDiagnost N90 / Precision CRF*** is substantially equivalent to the currently marketed and predicate device ProxiDiagnost N90 (K212837) in terms of the of design features, technological characteristics, indications for use, and safety and effectiveness.
Additionally, substantial equivalence was demonstrated with non-clinical performance tests and testing as per FDA-recognized consensus standards. The test results demonstrate that the device conforms to its specifications and is safe and effective for its intended use.