September 21, 2021

Philips Medical Systems DMC GmbH
% Supriya Dalvi
Regulatory Operations Specialist
Roentgenstrasse 24-26
Hamburg, Hamburg 22335
GERMANY

Re: K212837
Trade/Device Name: ProxiDiagnost N90
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, KPR
Dated: September 3, 2021
Received: September 7, 2021

Dear Supriya Dalvi:

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,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.09.21 14:29:22 -04'00'

, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212837

Device Name

ProxiDiagnost N90

Indications for Use *(Describe)*

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.

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 of Safety and Effectiveness K212837

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

Preparation Date:	September 3rd 2021	
510(k) Owner:	Philips Medical Systems DMC GmbH Roentgenstrasse 24 22335 Hamburg GERMANY Establishment registration number: 3003768251	
Contact:	Dr. Supriya A. Dalvi Regulatory Operations Specialist Phone: +91 9825604544 / +91 8733918445 Fax: +49 40 5078-2425 E-mail: supriya.dalvi@philips.com	
Proposed Device	Device Name	ProxiDiagnost N90
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Image-intensified fluoroscopic x-ray System
	Classification Regulation:	21 CFR Part 892.1650
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	JAA; KPR
Predicate Device	Device Name	ProxiDiagnost N90 (K173433, February 5, 2018)
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR Part 892.1650
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	OWB; JAA
Reference Device # 1	Device Name	CombiDiagnost R90 (K203087, December 3rd, 2020)
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Image-intensified fluoroscopic x-ray System
	Classification Regulation:	21 CFR Part 892.1650
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	JAA, KPR, MQB

Reference Device # 2	Device Name	DigitalDiagnost C90 (K202564, September 30th, 2020)
	Legal Manufacturer	Philips Medical Systems DMC GmbH
	Classification Name:	Stationary x-ray system
	Classification Regulation:	21 CFR 892.1680
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	KPR, MQB, LLZ
Device Description:	The ProxiDiagnost N90 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. The ProxiDiagnost N90 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 by -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. The ProxiDiagnost N90 retrieves images by means of a Cesium Iodide flat panel detector. Philips fluoroscopy systems (standard configuration) consist 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. The Eleva software of the proposed ProxiDiagnost N90 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 ProxiDiagnost N90 uses the same workflow from the currently marketed and predicate device, ProxiDiagnost N90 (K173433) with only the following modifications: - Inclusion of Extended reviewing options (like the optional reference monitor & remote control), - Inclusion of some image processing features	

<table>
<tr><td></td><td>- Updates to Operating system and Eleva application Software to include state-of-art operating system and incorporate the changes
- Replacement of the ceiling suspension with that of reference device, DigitalDiagnost C90 (K202564)
- Updates to improve serviceability
- Option for upgradability of Predicate device (K173433) to include the above changes</td></tr>
<tr><td>Indications for Use:</td><td>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.</td></tr>
<tr><td>Fundamental Scientific Technology:</td><td>The proposed ProxiDiagnost N90 employs the same basic construction, fundamental scientific technology and workflow as the predicate device, ProxiDiagnost N90 (K173433,) with regards to the functionality of all its components. It has the same high voltage generator, X-ray tube, Collimator, detectors, workstation (ELEVA) for images post-processing, storage and viewing.

The changes with respect to the predicate are mainly with the incorporation of the features that are already cleared on the reference devices; CombiDiagnost R90 (K203087) & DigitalDiagnost C90 (K202564). These changes are evaluated through ISO 14971 risk analysis procedures. These changes are addressed by the system and software verification testing of the proposed device. The test results support that the proposed ProxiDiagnost N90 is safe and effective. Refer Table 1 below for comparison of the technological characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K173433)

Table 1: Comparison of the Technological Characteristics of the proposed device and predicate device, ProxiDiagnost N90 (K173433)

<table>
<tr><th></th><th>Predicate device,
ProxiDiagnost N90 (K173433)</th><th>Proposed device,
ProxiDiagnost N90</th></tr>
<tr><td>Legal Manufacturer</td><td>Philips Medical Systems DMC GmbH</td><td>Identical</td></tr>
<tr><td>Classification</td><td>Class II per 21 CFR Part 892.1650, Primary Product code: OWB
Secondary Product code: JAA</td><td>Class II per 21 CFR Part 892.1650, Primary Product code: JAA
Secondary Product code: KPR

The proposed device is not interventional X-ray system</td></tr>
<tr><td>Regulation Name</td><td>Stationary x-ray system</td><td>Identical</td></tr>
<tr><td>Class</td><td>II</td><td>Identical</td></tr>
<tr><td>Review Panel</td><td>Radiology</td><td>Identical</td></tr>
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</table>

		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
		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
		Components	Table features	Identical
			Generator	Identical
			Tube	Identical
			Fixed Detector (Fluoroscopy)	Identical
			Collimator (Fluoroscopy)	Identical
			Grid	Identical
			System Control	Identical
		Extended reviewing options	Bluetooth remote control	Infrared remote control for Image Navigation It is identical to the reference device, CombiDiagnost R90 (K203087)
			Optional Reference monitor not available	Additional monitor for reference image support is available. It is identical to the reference device, CombiDiagnost R90 (K203087)
		Image processing functionality	Optional DSA (Digital Subtraction Angiography) feature not available	Digital Subtraction Angiography functionality is available and used for angiography and provides interactive viewing operations on a vascular run, so that the vascular anatomy becomes visible. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Predefined annotations integrated into the dynamic viewer not available	This feature enables the user to assign annotation to the image with

				the help of set of predefined annotations. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Optional Bone Suppression feature not available	Bone Suppression is a available which is a post-processing application intended to generate a secondary digital radiographic image of the chest. It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
			• Dynamic UNIQUE (Fluoroscopy only) • UNIQUE (radiography modality)	• Dynamic UNIQUE (fluoroscopy modality only)- no change • UNIQUE 2 (radiography modality only)- It is an improved ability for global contrast enhancement and a more sophisticated noise suppression. It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
			Less intuitive user interface and parameter names used in UNIQUE not self-explanatory.	An intuitive way of modifying the available parameters is introduced on the Eleva user interface. It is identical to that on the reference device, DigitalDiagnost C90 (K202564).
			Deviation and Target Exposure Indices not available	Deviation Index (DI) is availle which quantifies the deviation of the Exposure Index (EI_s) from the Target Exposure Index (EI_T). This feature is used by the clinical user to identify whether a certain image has been correctly exposed. It is identical to that on the reference device, DigitalDiagnost C90 (K202564).
			Optional SkyFlow function (grid-like image contrast for examinations) is activated only for chest AP/PA imaging.	Optional Skyflow is extended to imaging of other anatomies with Skyplate detector. It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
			Access to and Export of Original Image Data not available	Access to and Export of Original Image Data is available. This feature enables the access an export of original image data (clean raw images without any modification) on the system.

				It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
			One Button Stores All (OBSA) Content and performance Improvement intended to save multiple active information / changes made by the user by click of a single button	OBSA additionally used by system for sending logfile (Alert files) to central data base (RSN, e.g., RADAR or M2M server) frequently by single button click. It is identical to that on the reference device, DigitalDiagnost C90 (K202564).
			View Selection for Changed X-Ray Generation Data Sets are enabled for change a data set only for current examination or the examinations that are using this data set.	These data sets can be additionally applied to subset of all examinations too that are using this data set. This feature is mainly used by the Philips clinical education Specialist. It is identical to that on the reference device, DigitalDiagnost C90 (K202564).
			Avoid Ghosting in Verification Images of Portable Detectors feature not available	The feature for avoiding Ghosting in Verification Images of Portable Detectors is available. It enables the system to display verification images on wireless (SkyPlate) detector without ghosting artifacts. It is identical to that on the reference device, DigitalDiagnost C90 (K202564).
		Software	Windows 7 Operating System	Windows 10 operating system. The upgrade to Window 10 is a part of routine software upgrade done by Microsoft. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Philips Dynamic Eleva Image Chain	Identical
			Image acquisition - Eleva Workspot (Increment 39)	Eleva Workspot (Increment 42) The Eleva software is upgraded to incorporate the new features. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
		Ceiling Suspension (optional) for Radiography examinations only)	Dimensions & Components	Identical
			<u>Tube Head control</u> • Foil buttons for tube head operation • The monochrome text display on the Tube Control Handle • The central break release switch on the control handle for	• The User interface on Eleva tube head is touch control. • 12” color graphics display with touch control functionality for tube head operation. • Control handle with flat capacitive sensor for releasing

			the ceiling suspension movement	brakes for the ceiling suspension movement It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
			<u>Collimator</u> • Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible • With light field indicator • Two lasers (external to the collimator) • Detector Calibration with a Filter external to the 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 It is identical to that on the reference device, DigitalDiagnost C90 (K202564)
		Service Features	Remote access for Firmware updates for the dynamic detector not available	Remote access for Firmware updates for the dynamic detector is available to perform firmware updates of the detector. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Monitoring of system key parameters is available	Additional provision is made in the proposed device to allow service personnel to extract logs of defined key system parameters for offline analysis too. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Performance Bridge is available	Additional provision is made in the proposed device for collection of DICOM information by the Performance Bridge Data collector for logs generation. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Remote Silent Logfile Export is not available	Provision is made for remotely exporting the log files for offline analysis of the service engineers It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			Configurable Philips Remote Server Upload not available	Automatic upload of the log file is configured to the Philips Remote service Server. It is identical to that on the reference device, CombiDiagnost R90 (K203087)
			SAN pulse diagram is used for monitoring SAN pulses during an	SAN pulses introduced for monitoring with the dynamic

<table>
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<tr><td></td><td>image acquisition with the static detectors.</td><td>detector in addition to the static detectors
It is identical to that on the reference device, CombiDiagnost R90 (K203087)</td></tr>
<tr><td></td><td>Diagnostic for Detectors - Communication quality indicator is not available</td><td>Diagnostic for Detectors feature enables the collection of diagnostic information from static (radiography) detector communication logs for monitoring and logging purpose

It is identical to that on the reference device, DigitalDiagnost C90 (K202564).</td></tr>
<tr><td rowspan="2"></td><td>Indication for Rough Detector Handling on Eleva UI Including History is not available</td><td>Indication for Rough Detector Handling feature provides information/ feedback to the user in case of rough handling of the wireless (SkyPlate detectors) handling on the Eleva user interface
It is identical to that on the reference device, DigitalDiagnost C90 (K202564).</td></tr>
<tr><td>No option for Alpha drive Upgradeability, Serviceability & Spare parts</td><td>Alpha drive Upgradeability, Serviceability & Spare parts feature provides the option of alpha movement on the system and the relevant serviceability and spare parts introduction
It is identical to that on the reference device, DigitalDiagnost C90 (K202564).</td></tr>
</table>

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, when compared to the legally marketed predicate device (K173433). This thus demonstrates the substantial equivalence of the proposed device with the predicate device (K173433).
</td></tr>
<tr><td>Summary of Non-Clinical and Clinical Performance Data:</td><td>This 510(K) premarket notification includes non-clinical performance testing.
Tests were performed on the proposed ProxiDiagnost N90 according to the following FDA recognized standards and guidance documents:

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)

</td></tr>
</table>

- 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 1.1 2015-04, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Recognition # 12-296)
- 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 # 5-40)
- 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)
- *Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices, issued September 1, 2016*
- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005*
- *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*

Refer 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 meets acceptance criteria and is adequate for its intended use. Risk assessment activities show that the risks are sufficiently mitigated.

Table 2: Testing Summary for the changes on the proposed device

Change	Verification / Validation Method(s)	Reference Device
1a. Remote control in the examination room for image navigation	Sub-system Verification (Eleva software)	Test protocol identical to reference device, CombiDiagnost R90 (K203087)
	System Verification	
1b. Reference monitor support (optional)	Sub-system Verification (Eleva software)	
	System Verification	
2a. DSA (Digital Subtraction Angiography)	Sub-system Verification (Eleva software)	Test protocol identical to reference device, CombiDiagnost R90 (K203087)
	System Verification	
	Image quality Testing	
2b. Predefined annotations integrated into the dynamic viewer	Sub-system Verification (Eleva software)	
2c. Bone suppression	Sub-system Verification (Eleva software)	Test protocol identical to reference device, DigitalDiagnost C90 (K202564)
	System Verification	
2d. Upgrade from UNIQUE-to-UNIQUE 2	Sub-system Verification (Eleva software)	
	System Verification	

	2e. Intuitive User Interface for Processing Parameters	Sub-system Verification (Eleva software)	
	2f. Deviation and Target Exposure Indices	Sub-system Verification (Eleva software)	
		System Verification	
	2g. Update of optional Skyflow feature	Sub-system Verification (Eleva software)	
		System Verification	
	2h. Access to and Export of Original Image Data	System Verification	
	2i. Improved OBSA (one button store all) for Content and performance Improvement	Sub-system Verification (Eleva software)	
		System Verification	
	2j. View Selection for Changed X-Ray Generation Data Sets	Sub-system Verification (Eleva software)	
	2k. Avoid Ghosting in Verification Images of Portable Detectors	System Verification	
	3a. Operating system upgrade to state of art operating system i.e. Microsoft Windows 10	Sub-system Verification (Eleva software)	Test protocol identical to reference device, CombiDiagnost R90 (K203087)
		System Verification	
	3b. Upgrade of Eleva Application software to increment 42 to accommodate software changes for all the relevant changes (Change # 1,2, 4, 5)	All the relevant Software functions are tested at system and subsystem level. (Refer testing for change # 1, 2, 4 and 5)	
	4a. Tube head control	System Verification	Test protocol identical to reference device, DigitalDiagnost C90 (K202564)
	4b. Collimator	System Verification	
	5a. Monitoring and Firmware Updates for Field Service	System Verification	Test protocol identical to reference device, CombiDiagnost R90 (K203087)
	5b. Remote access for the field service Engineer	Sub-system Verification (Eleva software)	
	5c. Service Diagnostic	System Verification	Test protocol identical to reference device, CombiDiagnost R90 (K203087) & DigitalDiagnost C90 (K202564)
	5d. Hardware upgrades	System Verification	Test protocol identical to reference device, DigitalDiagnost C90 (K202564)
	6. Option for upgradebility of Predicate device	All the relevant Software functions are tested at system and subsystem level. (Refer testing for change # 1, 2, 3 and 5 a,b,c)	
	There is no clinical data submitted in this 510(k) premarket notification.		
Substantial Equivalence Conclusion:	The comparison of intended use, design features, technological characteristics, non-clinical performance data, and safety testing demonstrates the proposed ProxiDiagnost N90 is substantially equivalent to the predicate device (K173433), demonstrating the proposed device to be safe and effective.		