October 19, 2023

Philips Medical Systems DMC GmbH
% Ming Xiao
Regulatory Affairs Manager
Röntgenstrasse 24
HAMBURG, HAMBURG 22335
GERMANY

Re: K232910
Trade/Device Name: CombiDiagnost R90
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, KPR
Dated: September 19, 2023
Received: September 19, 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
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)*

K232910

Device Name

CombiDiagnost R90

Indications for Use *(Describe)*

The CombiDiagnost R90 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

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

Preparation Date:	September 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 Phone: +49(40) 34971-2306 E-mail: ming.xiao@philips.com
Secondary Contact:	Shalin Dave Senior Regulatory Affairs Project Manager Phone: +31(6) 42532604 E-mail: shalin.dave@philips.com
Proposed Device	
Device Name	CombiDiagnost R90
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
Product Code:	JAA, KPR
Predicate Device	
Device Name	CombiDiagnost R90 (K203087, December 03, 2020)
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
Product Code:	JAA, KPR, MQB
Reference Device # 1	
Device Name	ProxiDiagnost N90 (K212837, cleared 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
Product Code:	OWB, JAA

Device Description:

The CombiDiagnost R90 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 CombiDiagnost R90 is a remote-controlled fluoroscopy system in combination with high-end digital radiography. The system is suitable for routine X-ray examinations and special examinations on patients in standing, seated or laying positions. The CombiDiagnost R90 retrieves images by means of a Cesum Iodide flat panel detector.

Philips fluoroscopy systems consist of the following components (standard configuration):

- Basic unit (also called "geometry" or "table unit")
- Workstation Eleva Workspot with integrated generator control, hand switch, keyboard, mouse, touch screen and PC
- Equipped with a dual screen-monitor as standard
- Spot film device (digital camera or flat panel detector)
- X-ray Generator Velara
- X-ray tube assembly mounted in above table mode to be remote controlled
- Receptor: Flat panel detector Optional components:
- Skyplate wireless portable detectors small and large
- Ceiling Suspension (CSM3)
- Vertical Wall stand (VS2)
- Ceiling Suspension for monitors
- Monitor trolley
- Remote control for RF viewer
- Accessories for "Stitching on the Table"

The **CombiDiagnost R90** uses the same workflow from the currently marketed and predicate device, CombiDiagnost R90 (K163210) with only the following modifications:

- additional optional components (like the reference monitor, remote control),
- Eleva Workspot updated to incorporate new imaging features mainly from the previously approved reference device, DigitalDiagnost C90 (K182973) along with functional clusters like Digital Subtraction Imaging and stitching on the table
- updates to improve usability and serviceability.

The Eleva software of the proposed CombiDiagnost R90 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 proposed CombiDiagnost R90 is same as the predicate device (K203087) with some modifications as described.

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 (K203087). 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.

Indications for Use:
CombiDiagnost R90 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.

Fundamental Scientific Technology:
The proposed CombiDiagnost R90 is substantially equivalent to the manufacturer's legally marketed devices:

- Predicate Device: CombiDiagnost R90, (K203087, SE date December 31, 2020), Philips Medical Systems DMC

A detailed comparison of the proposed and predicate device (K203087) is provided in **Table 1.**

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, CombiDiagnost R90 (K203087)

	Predicate Device, CombiDiagnost R90 (K203087)	Proposed Device, CombiDiagnost R90
Legal Manufacturer	Philips Medical Systems DMC GmbH	Identical
Classification	Class II per 21 CFR Part 892.1650, Primary Product code: JAA Secondary Product code: KPR, MQB	Identical
Regulation Name	Stationary x-ray system	Identical
Class	II	Identical
Review Panel	Radiology	Identical
Indications for Use	CombiDiagnost R90 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
Energy Source	X-ray	Identical
Principle of Operation	CombiDiagnost R90 is intended for the medical application procedures radiography and fluoroscopy. Depending on the specific indication, X-ray procedures vary in patient positioning and the modification of radiographic parameters. The system is suitable for routine X-ray examinations and special examinations on patients in standing, seated or laying positions, depending on the specific indication.	Identical
Table Features		
Working height (table top center to floorplate)	65 cm – 133 cm	Identical
Table tilt movement	-90° to +90°	Identical
Table top suspension	Two sides suspensions	Identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, CombiDiagnost R90 (K203087)

	Predicate Device, CombiDiagnost R90 (K203087)	Proposed Device, CombiDiagnost R90
Table top material	Plastic laminate or carbon fiber	Identical
Table top movement	Lateral: 32 cm (12.6") (± 16 cm (6.3")) Longitudinal: Only detector movements to improve patient comfort	Identical
Table top absorption	Plastic, with Carbon fiber: 0.6mm Al @ 100kV, HVL = 3.6mm Al	Identical
Maximum patient weight	284 kg (626 lbs)	Identical
Lateral scan distance	32 cm ± 16 cm	Identical
Lateral scan speed	5 cm/s, soft start and stop Auto centering	Identical
Longitudinal scan distance	148 cm (58.3") longitudinal, motorized	Identical
Longitudinal scan speed / Detector movement	3 cm – 20 cm / sec	Identical
Table column angulation	-40° to +40°	Identical
Source image distance	113cm – 183cm	Identical
Other Components		
Generator	Philips Velara GCF/RF, 65 kW, optional 80 kW SPDU initial version (4512-202-03291)	Philips Velara GCF/RF, 65 kW, optional 80 kW SPDU upgrade version (4512-202-03293) This functionality has been verified to have no impact on the product safety and effectiveness of the proposed device. It is substantial equivalent to reference device ProxiDiagnost N90 (K212837).
Tube	Philips SRO 33100 ROT 380 or SRM 0608 ROT GS 505	Identical
Fixed Detector (Fluoroscopy)	Pixium FE 4343 F	Identical
Fixed Detector (Optional for Radiography)	Pixium 4343RCE	Pixium 4343RCE2 Substantial equivalent, This change has no impact on product Intended Use, safety, functionality, performance and effectiveness.

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, CombiDiagnost R90 (K203087)

Modulation Transfer Function (MTF) (according to IEC 62220-1-3 standard)	lp/mm % 1 66 2 35 3 19 3.4 15	lp/mm % 1 63 2 35 3 19 3.4 15 has Similar, the MTF emained the same, with on decrease, thus, ov

	Predicate Device, CombiDiagnost R90 (K203087)	Proposed Device, CombiDiagnost R90
		there is no impact to safety and effectiveness.
Detective Quantum Efficiency (DQE) (according to IEC 62220-1-3 standard)	DQE at 2 µGy lp/mm % 0.05 65 1 51 2 41 3 27 3.4 18	DQE at 2 µGy lp/mm % 0.05 69 1 51 2 41 3 27 3.4 18 Similar, the DQE has remained essentially the same, with one slight increase, thus, overall, there is no impact to safety and effectiveness.
System Control	Remote, optional nearby with nearby control trolley	Identical
Collimator (Fluoroscopy)	Motorized automatic collimation	Identical
Grid	Parkable	Identical
Image Acquisition	Eleva WorkSpot	Identical
Operating System	Microsoft Windows 10	Identical
Image Processing	UNIQUE 2	Identical
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
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
Image processing functionality		
Bone Suppression (Optional)	Bone Suppression post-processing application is available. It is intended to generate secondary digital radiographic image of the chest by suppressing bones from the original image.	Identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, CombiDiagnost R90 (K203087)

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
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
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

	Predicate Device, CombiDiagnost R90 (K203087)	Proposed Device, CombiDiagnost R90
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
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
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
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
Software		
Operating System	Windows 10	Identical
Image Chain (fluoroscopy)	Philips Dynamic Eleva Image Chain	Identical
Image acquisition	Eleva Workspot (Increment 42)	Identical
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
Movement	3440 mm to 6140 mm	Identical
Transverse travel	1500 mm to 3220 mm	Identical
Vertical travel	1650mm to 1705mm	identical

Table 1 Comparison of the Technological Characteristics of the proposed device and predicate device, CombiDiagnost R90 (K203087)

	Predicate Device, CombiDiagnost R90 (K203087)	Proposed Device, CombiDiagnost R90
	• 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	
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
Wireless detector (Optional) in vertical stand and table bucky (Radiography)	• SkyPlate Large (pixium 3543EZ) • SkyPlate Small (pixium 2430EZ)	Identical
SkyPlate Detector Sharing	Yes	Identical
Tube	High power X-ray Tube, Philips SRO 33100 ROT 380 or SRM 0608 ROT GS 505	Identical
Automatic Image Stitching (Optional)	Yes	Identical
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
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. • Control Handle: Control handle with flat capacitive sensor for releasing brakes for the ceiling suspension movement.	Identical
Collimator	• Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible • With light field indicator	Identical

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 CombiDiagnost R90, when compared to the legally marketed predicate device (K203087). This thus demonstrates the substantial equivalence of the proposed device with the predicate device (K203087).

Summary of Non-Clinical and Clinical Performance Data:

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: The verification and validation methods (test methods and acceptance criteria) used to evaluate the proposed CombiDiagnost R90 are the same as those used for the predicate device (K203087) 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 1.1 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

The proposed device 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 (K203087). 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 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 (K203087). The software for the proposed device has the same 'Level of concern (Moderate)' as that of the predicate device (K203087). The software verification testing has been conducted as per the level of concern.

The proposed device 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 (K203087).

The proposed device complies with Guidance for Radio Frequency Wireless Technology in Medical Devices, issued August 14, 2013. All the radiofrequency components of the predicate device (K203087) 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 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: o Identification of assets, threats, and vulnerabilities;

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

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 CombiDiagnost R90 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

Tests	Document number	Test results
System Verification testing	• D000710352: System Verification Report CombiDiagnost R90 Rel. 1.1.1 & 1.1.2 • D000906247, System Verification Report CombiDiagnost R90_R1.1.4 • D001021873: SVR_CombiDiagnost R90_R1.1.5	Pass System verification test activities substantiate that the system conforms to the system requirements
Software verification testing	• D000693721: Verification report SubSystem Eleva Inc.42.1 • D000457609: Subsystem Verification Report R1.1.4 • D001012699: Subsystem Verification Report 42.0 Combi R1.1.5 • D000185012: Configuration Management Plan Eleva • D000560160: TEST Report IEC 62304 Medical device software – Software life-cycle processes including software maintenance plan	Pass Software verification test activities substantiate that the software conforms to the requirements
Risk control	• D000234134: Risk Matrix Status Report for CombiDiagnost R90 • D000188652: RMSR for subsystem Eleva	Pass System meets the defined risk control measures
Cyber Security	• D000584899: Cyber Security Plan CombiDiagnost R90 • D000256905: Cyber Security Risk Management Matrix CombiDiagnsot R90 • D000585130: Cyber Security Risk Statement CombiDiangost R90 • D000513810: Manufacturer Disclosure Statement for Medical Device Security for CombiDiagnost R90 • D001393076: SBOM	Pass Verification test activities substantiate that the system meets the defined security risk control measures

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

Substantial Equivalence Conclusion:
The proposed device, CombiDiagnost R90 is substantially equivalent to the currently marketed and predicate device, (K203087) 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 demonstrates that the device conforms to its specifications and is safe and effective for its intended use.