December 17, 2024

Philips Medizin Systeme Böblingen GmbH
Angel Ya
Regulatory Affairs Manager
Hewlett-Packard Strasse 2
Böblingen, 71032
Germany

Re: K241556
Trade/Device Name: Cardiac Workstation (5000); Cardiac Workstation (7000)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 19, 2024
Received: November 19, 2024

Dear Angel Ya:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241556

Device Name

Cardiac Workstation (5000);
Cardiac Workstation (7000)

Indications for Use *(Describe)*

The Cardiac Workstation is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze and store these ECG signals for review by the user. They are to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over-read and validate (or change) the computer-generated ECG interpretation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary			
I. SUBMITTER			
Date Prepared	14 May 2024		
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard Strasse 2 71032 Böblingen GERMANY Phone: +1 (949)-502-1823		
Key Contact	Angel Ya Regulatory Affairs Mgr. Email: angel.ya@philips.com		
510(k) Submission Type	This is a Traditional 510(k).		
II. DEVICE			
Trade Name	Cardiac Workstation 5000 (aka: CW 5000) Cardiac Workstation 7000 (aka: CW 7000)		
Common Name	Cardiograph		
Classification Name	Review Panel: Cardiovascular Regulation Description: Electrocardiograph 21 CFR §870.2340 Regulatory Class: II Product Code: DPS		
III. PREDICATE DEVICE			
Predicate Device	***510(k) No.***	***Company Name Device Name***	***Product Code***
	K210560	Philips Medical Systems PageWriter TC70 Cardiograph	DPS
Reference Device	K221141	Philips Medizin Systeme Böblingen GmbH PageWriter TC35 Cardiograph	DPS
The Philips Cardiac Workstation 5000 and Cardiac Worksation 7000 are substantially equivalent to the legally marketed predicate, PageWriter TC70 Cardiograph (K210560).			
IV. DEVICE DESCRIPTION			
Cardiac Workstation 5000 and **Cardiac Workstation 7000** – description of the device per 21 CFR			

807.92(a) (4)

The Cardiac Workstation 5000 (aka: CW 5000) and Cardiac Workstation 7000 (aka: CW 7000) are intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze and store these ECG signals for review by the user. They are to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements are offered to the clinician on an advisory basis only. They are to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over-read and validate (or change) the computer-generated ECG interpretation.

The CW 5000 and CW 7000 are mid- and high-range interpretive cardiographs, differing primarily in display size, the number of standard options. Both devices offer a full array of features built on the Linux operating system, with touch screen operation, a configurable feature set, and interpretation from the clinically proven Philips DXL ECG Algorithm (K132068). They provide a cardiograph solution for hospitals and cardiology clinics in processing large volumes of ECGs. The DXL ECG algorithm in the software analyzes up-to 18 leads of simultaneously acquired ECG waveform to interpret rhythm and morphology for a variety of patient populations. The measurements are then analyzed by the DXL ECG Algorithm. The resulting ECG reports may include or exclude ECG measurements, reasons, or analysis statements. The algorithm covers both adult and pediatric populations.

The CW 5000 and CW 7000 consist of the following:

- An electrocardiograph device with integrated display and printer. CW 5000 provides 12.1'' display panel. CW 7000 provides 15.6'' and 18.5'' options for the display panel.
- Optional Trolley (ordered via a separate part number)

The subject devices are further structured with options relating to software, hardware, UI language, keyboard locale, and a wide range of other configuration choices to optimize the user's experience with the devices.

V. INDICATIONS FOR USE

Comparison of Indications for Uses for Subject Device and Predicate

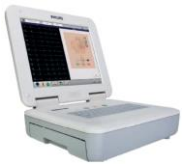
PageWriter TC70 Cardiograph ***Predicate,*** K210560	Cardiac Workstation 5000 (aka: CW 5000) Cardiac Workstation 7000 (aka: CW 7000) ***Subject Device***	**Description of differences**
Philips PageWriter TC70 cardiograph is intended to acquire multichannel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. It is to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.	The Cardiac Workstation is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze and store these ECG signals for review by the user. They are to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over-read and validate (or change) the computer-generated ECG interpretation.	Identical except for change to product name.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Similarities

Item of Comparison	Description/Rationale
Indications for use	The CW 5000 and CW 7000 subject devices and the currently marketed predicate device (K210560) PageWriter TC70 Cardiograph have the identical indications for use. Both CW 5000 and CW 7000 and TC70 are intended to acquire multi-channel ECG signals from patient and to record, display and store those signals to be review by the user. The use environment is identical between CW 5000, the CW 7000, and the predicate device, TC70. They are all to be used in healthcare facilities by professionals.

Fundamental scientific technologies and performances	Both CW 5000 and CW 7000 and PageWriter TC70 Cardiograph are similar with respect to the fundamental scientific technologies. They are electrocardiographs that collect multi-channel ECG signals of adult and pediatric patients from body surface ECG electrodes. These ECG signals are amplified, digitized, and processed in the digital domain. The cardiograph records, displays, analyzes (through the cleared ECG algorithm in K132068), and prints the processed ECG signals for review by the clinical operator. The CW 5000 and CW 7000 use the same fundamental design as the TC70, but also contain improvements to the user's experience by deploying updated hardware and software technologies. The devices also incorporate minor changes to the ECG signal processing approach and security improvements to comply with widely recognized standards. Both devices use the same cleared ECG algorithm (PH110C) for ECG measurement and interpretation.
Patient Type	Adult and pediatric patients
Patient Data Cable	The subject devices use the same patient cable cleared under K080999 with the predicate device, PageWriter TC70 Cardiograph. The latest 510k for the predicate device is K210560.
Use Environment	The use environment is identical between the subject CW 5000 and CW 7000 devices and the predicate device (K210560) PageWriter TC70 Cardiograph. They are intended for use in a professional healthcare facility. They are not for home use, and not intended to be used together with any RF emitting equipment such as high-frequency electrosurgical equipment, diathermy, or electrocautery.
Connectivity	The subject CW 5000 and CW 7000, like the predicate device (K210560) PageWriter TC70 Cardiograph, provide LAN and wireless connectivity. This functionality is used to transmit ECG reports, patient order/ADT info, device configuration details, and time sync between the Cardiac Workstation and ECG Management Systems, Device Management Dashboard, and the hospital's EMR.
ECG Performance	Compared to the predicate device (K210560), PageWriter TC70 Cardiograph, the subject CW 5000 and CW 7000 devices provide similar performance on ECG acquisition of up to 18 leads, algorithm interpretation, display accuracy, and ECG report formats for printing and transmission purposes.
Safety and EMC performance	The subject CW 5000, CW 70000, and predicate device (K210560) PageWriter TC70 Cardiograph have the same level of safety and EMC performance. The safety classification of both subject and predicate device (K210560) is class I, with CF type of applied part. The EMC emission classification is Group I, Class B.

Differences	
Item of Comparison	**Description/Rationale**
Physical features and parameters	The CW 5000 and CW 7000 device's physical features and size are similar to the predicate device (K210560) PageWriter TC70 Cardiograph. A picture of the subject devices and predicate is provided below.  **Cardiac Workstation 5000**  **Cardiac Workstation 7000**  **Philips TC70 Cardiograph** Compared to the predicate device (K210560), the Cardiac Workstations have a similar product configuration, including an LCD touch screen, embedded printer, power supply module, PIM and Trolley. The CWs have an array of touchscreen options (12.1 in for CW5000, 15.6 in and 18.5 in for CW7000) and 2 optional trolley types: height-adjustable and fixed-height. The external ports are similar. The rear of the device provides the USB ports and connectors for LAN, PIM, and power cord. The right side houses the battery compartment door, and the left side has the paper drawer.
ECG signal acquisition	Compared to the predicate device, PageWriter TC70 Cardiograph (K210560), the Cardiac Workstations provide improved ECG A/D signal processing resolution from 12 to 24 bit. The digital data processing rate has improved from 500 to 1000 SPS (Samples Per Second). ECG signal bandwidth has been improved from 0.05Hz~150 Hz to 0.02Hz~300 Hz. The subject device also supports the latest Philips ECG XML schema 1.04.04. The improved digital data processing and filter range are identical with reference device, Pagewriter TC35 (K221141).
Radio connection	Compared to the predicate device, PageWriter TC70 Cardiograph (K210560), the wireless module used for the subject device provides updated compatibility to support communication protocol 802.11 ac (WiFi 5). The wireless module, wireless function, specification, transmitting data, and connecting system/application at the hospital environment are the same as the reference device, Pagewriter TC35 (K221141).
Security Enhancement	Compared to the predicate device, PageWriter TC70 Cardiograph (K210560), the subject device provides improved cybersecurity risk control. The operating system has been changed from the "end of support" WinCE5/WinCE7 OS to the supported Linux OS. The device supports FIPS 140-2 for data encryption, user authentication, USB disk encryption and digital signature, and supports SMB

	V2/V3. The improved performance is identical to the reference device, Pagewriter TC35 (K221141).

Substantial Equivalence Summary
Analysis of operational, technological and safety characteristics form the basis for the determination of substantial equivalence of the subject device, Cardiac Workstation 5000 and Cardaic Worksation 7000, with the legally marketed predicate device (K210560). The Cardiac Workstation 5000 and Cardiac Workstation 7000 are substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

Non-Clinical Tests – Harmonized Standards

The subject Cardiac Workstation 5000 and Cardiac Workstation 7000 have passed all safety, electromagnetic compatibility, and cybersecurity tests to demonstrate compliance with the harmonized standards below.

Standard	FDA Recognition #	Title
ANSI/AAMI ES60601-1:2005/A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	19-46	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	19-36	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests
ANSI AAMI IEC 60601-2-25:2011/(R)2016	3-105	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-1-6: 2010+A1:2013+A2: 2020	5-132	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1: 2015+A1: 2020	5-129	Medical devices. Part 1: Application of usability engineering to medical devices
ANSI AAMI IEC 62304:2006/A1:2016	13-79	Medical device software - Software life cycle processes
ANSI C63.27:2021	19-48	American National Standard for Evaluation of Wireless Coexistence

AAMI TIR69:2017/(R2020)	19-22	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
ASTM D4169:2022	14-576	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 14971:2019	5-125	Medical devices - Application of risk management to medical devices
AIM 7351731:2021	19-45	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
ISO 15223-1:2021	5-134	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 20417:2021	5-135	Medical devices - Information to be supplied by the manufacturer

Non-clinical Bench Tests

Non-clinical bench testing activities established the performance, functionality, and reliability characteristics of the subject Cardiac Workstation 5000 and Cardiac Workstation 7000. This testing covered verification of performance in the domains of software, environment, reliability, mechanical, hardware, packaging, human factors and usability performance. The Cardiac Workstation 5000 and Cardiac Workstation 7000 were evaluated against all applicable external standards and internal procedures, and successfully passed all verifications and validations. The results demonstrate that Cardiac Workstation 5000 and Cardiac Workstation 7000 meet the performance claims and support a determination of substantial equivalence to the predicate PageWriter TC70 Cardiograph (K210560).

Clinical Studies

The Cardiac Workstation 5000 and Cardiac Workstation 7000, like the predicate device (K210560), did not require clinical studies to demonstrate substantial equivalence.

FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have all been applied/conducted for the Cardiac Workstation 5000 and Cardiac Workstation 7000.

Based upon the design, indications for use, classification, usability, and safety testing, the Cardiac Workstation 5000 and Cardiac Workstation 7000 are substantially equivalent to the predicate device (K210560).

VIII. CONCLUSIONS

The results of the substantial equivalence assessment, evaluated alongside non-clinical bench testing, electrical safety, electromagnetic compatibility, software verification and validation, human factors and usability, demonstrate that the Cardiac Workstation 5000 and Cardiac Workstation 7000 can be considered to be substantially equivalent to the predicate device (K210560). The subject devices perform as intended and have performance characteristics that are substantially equivalent to the PageWriter TC70 Cardiograph predicate device (K210560).