December 2, 2022

Medizin Systeme Boblingen GmbH
Judy Yang
Regulatory Affairs Manager
Hewlett-Packard Strasse 2
Boblingen, 71032
Germany

Re: K221141
Trade/Device Name: PageWriter TC35 Cardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 2, 2022
Received: April 19, 2022

Dear Judy Yang:

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,

for Shruti N. Mistry -S

Jennifer Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221141

Device Name
PageWriter TC35 Cardiograph

Indications for Use *(Describe)*

The PageWriter TC35 Cardiograph 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. 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.

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	8 April 2022		
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard Strasse 2 71032 Böblingen GERMANY Phone: +1 (949)-502-1823		
Key Contact	Judy Yang Regulatory Affairs Mgr. Email: judy.yang_1@philips.com		
510(k) Submission Type	This is a Traditional 510(k).		
II. DEVICE			
Trade Name	PageWriter TC35		
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 TC20 Cardiograph	DPS
The PageWriter TC35 Cardiograph is substantially equivalent to the legally marketed predicate, PageWriter TC20 Cardiograph (K210560).			
IV. DEVICE DESCRIPTION			
PageWriter TC35 Cardiograph – description of the device per 21 CFR 807.92(a) (4)			
The PageWriter TC35 Cardiograph is intended to acquire, record, analyze and store multi-channel ECG signals from adult and pediatric patients through a body surface ECG electrode. The device is integrated with the cleared algorithm (K132068) to provide measurements, and interpretations for review by the clinical on an advisory basis. The interpretated ECG with measurement and interpretative statements are to be used in conjunction with 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.

PageWriter TC35 Cardiograph has LCD display with touchscreen, keyboard and functional buttons. The device can be powered from AC power or through an embedded re-chargeable battery. The device contains built-in thermal printer for ECG report printing. The device contains USB ports, LAN port and optional WiFi interface for communications.

PageWriter TC35 Cardiograph has various configurations provided for the preference of the user, and it can be updated with the compatible options/modules from the corresponding upgrade Kit (the upgrade kit is not considered as a device kit, refer to the **Table 10-2** for the details of configuration list) for use with all approved accessories and spare parts, including patient cables, electrodes, print papers and trolleys. None of the accessories and spare parts are provided sterile.

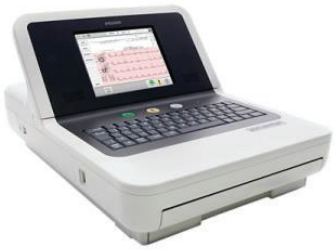
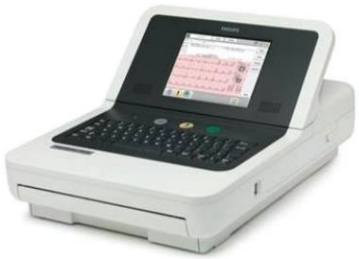
Once configured, PageWriter TC35 cardiograph can provides integrated connectivity (wired or wireless) with the compatible Philips IntelliSpace ECG Management System, IntelliBridge Enterprise (IBE), DICOM for patient order download and ECG report transmission. The cybersecurity on PageWriter TC cardiograph is periodically and proactively improved according to the cybersecurity analysis and the routine device cyber maintenance plan.

V. INDICATIONS FOR USE

Comparison of Indications for Uses for Subject Device and Predicate

PageWriter TC20 Cardiograph ***Predicate,*** K210560	PageWriter TC35 Cardiograph ***Subject Device***
Philips Electrocardiograph, Page Writer TC cardiograph (TC20) 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.	Identical

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Similarities	
Item of Comparison	**Description/Rationale**
Indications for use	The subject device PageWriter TC35 Cardiograph and the currently marketed predicate device (K210560) PageWriter TC20 Cardiograph have the identical indications for use. Both TC35 and TC20 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 TC35 and the predicate device TC20, to be used in healthcare facilities by professional user.
Fundamental scientific technologies and performances	Both PageWriter TC35 Cardiograph and PageWriter TC20 Cardiograph are similar with respect to the fundamental scientific technologies. They are Electrocardiographs to 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), and prints the processed ECG signals for review by the clinical operator. PageWriter TC35 Cardiograph uses the similar design including software feature and hardware feature with minor change on ECG signal acquisition and security improvement. They are use the same cleared ECG algorithm PH110C for ECG measurement and interpretation.
Patient Type	Adult and Pediatric patients
Use Environment	The use environment is identical between subject device PageWriter TC35 Cardiograph and the predicate device (K210560) PageWriter TC20 Cardiograph. They are intended to be used in the professional healthcare facility environment. Not for home use, and not intended to be used together with any RF emitter equipment such as high-frequency electrosurgical equipment, diathermy, or electrocautery.
Physical features and parameters	The PageWriter TC35 Cardiograph device physical feature and physical size is identical as the predicate device (K210560) PageWriter TC20 Cardiograph. A picture of the subject device and predicate is provided below.   PageWriter TC35 Cardiograph PageWriter TC20 Cardiograph Same as the predicate device (K210560), the subject device provides the same size of LCD touch screen, keyboard, embedded printer, power module and battery. The provided external ports are also the same, rear side of the device provide Patient Cable connector, LAN connector, USB port and power cord connector, while right side of the device provide another USB port, and battery compartment door.
Connectivity	The subject PageWriter TC35 Cardiograph and the predicate device (K210560) PageWriter TC20 Cardiograph both provide LAN and Wireless connection. The

	LAN and wireless function for both TC35 and TC20 are used to transmit the ECG reports, patient order/ADT, device configuration and time sync between the Cardiograph and the external device like ECG management system, DICOM, Dashboard and hospital servers.
ECG Performance	Compared to the predicate device (K210560) PageWriter TC20 Cardiograph, the subject PageWriter TC35 Cardiograph provide the same performance on 12-lead ECG acquisition, algorithm interpretation, display accuracy, and ECG report formats for printing and transmitting purpose.
Safety and EMC performance	The subject PageWriter TC35 Cardiograph and the predicate device (K210560) PageWriter TC20 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. And the EMC emission classification is Group I, Class B.
Differences	
Item of Comparison	**Description/Rationale**
Patient Data Cable	The subject device uses different part number of patient cable to connect to the electrode to transmit ECG signal. The patient cable is form, fit and functionally identical to the predicate device (K210560) as cleared together with PageWriter TC20 Cardiograph, the minor difference is on the thumb screw to match the mechanical connector at the Cardiograph end. 989803184921 12-Lead Patient Cable (IEC), Standard Length 989803184931 12-Lead Patient Cable (AAMI), Standard Length 989803184941 12-Lead Patient Cable (IEC), Long 989803184951 12-Lead Patient Cable (AAMI), Long
ECG signal acquisition	PageWriter TC35 Cardiograph provide improved performance on ECG signal process. The sampling rate of the subject device have been improved to 1000 samples per second, while the predicate device (K210560) PageWriter TC20 Cardiograph sampling rate is 500 samples per second. TC35 provide ECG signal bandwidth from 0.02Hz~300 Hz, while TC20 bandwidth is 0.05Hz~150 Hz.
Radio connection	Compared to the predicate device (K210560), the wireless module to be used on the subject device provides compatibility to the latest version of 802.11 standard.
Security Enhancement	Compared to the predicate device (K210560), the subject device provided improvement on cybersecurity risk control. The operating system has changed from the end of supported WinCE5 to Linux. The device support of FIPS 140-2 for data encryption, provide role-base access management, USB disk encryption and digital signature, support SMB V2/V3.

Substantial Equivalence Summary
Operational, technological and safety characteristics form the basis for the determination of substantial equivalence of the subject device, PageWriter TC35 Cardiograph, with the legally marketed predicate device (K210560). The PageWriter TC35 Cardiograph is substantially equivalent to the predicate devices.
VII. PERFORMANCE DATA
Non-Clinical Tests – Harmonized Standards

The subject PageWriter TC35 Cardiograph has 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	19-4	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.0 2014-02	19-8	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests
IEC 60601-2-25 Edition 2.0 2011-10	3-105	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-1-6 Edition 3.1 2013-10	5-89	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Edition 1.0 2015-02	5-114	Medical devices. Part 1: Application of usability engineering to medical devices
IEC 62304 Edition 1.1 2015-06	12-79	Medical device software - Software life cycle processes
AAMI TIR69:2017	19-22	Technical Information Report Risk management of radiofrequency wireless coexistence for medical devices and systems
ANSI IEEE C63.27- 2017	19-29	American National Standard for Evaluation of Wireless Coexistence
ASTM D4169-16	14-499	Standard Practice for Performance Testing of Shipping Containers and Systems
ANSI AAMI EC53:2013	3-129	ECG trunk cables and patient lead-wires
ISO 14971:2019	5-125	Medical devices - Application of risk management to medical devices
AIM 7351731:2017	19-30	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

Non-clinical Bench Tests

Non-clinical bench testing activities establish the performance, functionality, and reliability characteristics of the subject device, PageWriter TC35 Cardiograph. Tests included software functional

verification, environment and reliability, mechanical and hardware, packaging, human factor and usability performance.

The PageWriter TC35 Cardiograph was evaluated against all applicable standards and internal procedures, and successfully passed all verifications, testing and validations. The results demonstrated that Philips PageWriter TC35 Cardiograph meets all safety, effectiveness and performance claims and supports a determination of substantial equivalence to the predicate PageWriter TC20 Cardiograph (K210560).

Clinical Studies

The PageWriter TC35 Cardiograph like the predicate device (K210560), it 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 been conducted for the PageWriter TC35 Cardiograph.

Based upon the design, indications for use, classification, usability, and safety testing, the PageWriter TC35 Cardiograph is substantially equivalent to the predicate device (K210560).

VIII. CONCLUSIONS

The results of the substantial equivalence assessment, evaluated alongside non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation, and human factors and usability demonstrate that the PageWriter TC35 Cardiograph does not raise different questions of safety and effectiveness when compared to the predicate (K210560). The subject device performs as intended, and has performance characteristics that are substantially equivalent to the PageWriter TC20 Cardiograph predicate device (K210560).