June 30, 2021

Philips Medical Systems
Hong Zhu
Sr. Regulatory Affairs Manager
Building A2, #718 Lingshi Road, Jingan District
Shanghai, Shanghai 200072
China

Re: K210560
Trade/Device Name: Page Writer TC20 Cardiograph, Page Writer TC30 Cardiograph, Page Writer TC50 Cardiograph, Page Writer TC70 Cardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: February 10, 2021
Received: March 22, 2021

Dear Hong Zhu:

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,

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)*
K210560

Device Name
Philips Electrocardiograph PageWriter TC20, TC30, TC50, TC70

Indications for Use *(Describe)*
Philips Electrocardiograph, PageWriter TC cardiograph (TC20, TC30, TC50, and TC70) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

510(k) Summary			
5.1 Submitter			
Date Prepared	30 June 2021		
Submitter/Owner	Philips Healthcare-VSS-Shanghai CDC A division of Philips Medical Systems Building A2, #718 Lingshi Road, Jingan District, Shanghai, China 200072		
Key Contact	Hong Zhu Sr. Regulatory Affairs Manager Telephone: +86 18501616553 Email: hong.zhu_2@philips.com		
510(k) Submission Type	This is a Special 510(k).		
5.2 Device			
Trade Name	PageWriter TC20, TC30, TC50, TC70		
Common Name	Cardiograph		
Catalog Number	TC20 (860332), TC30 (860306), TC50 (860310), TC70 (860315)		
Classification Name	Panel & Name: Electrocardiograph Subpart & Division: 21 CFR § 870.2340 Regulatory Class: Class II Product Code: DPS		
5.3 Predicate Device			
Predicate Device	***510(k) No.***	***Company Name Device Name***	***Product Code***
	K191738	Philips Medical Systems PageWriter TC20, TC30, TC50, TC70	DPS
Reference Device	K052049, K073376, K132068	Philips Medical Systems Philips DXL 12/16-Lead ECG Algorithm	DPS
PageWriter TC20, TC30, TC50, TC70 with the addition of vectorcardiograph (VCG) function is substantially equivalent to the legally marketed predicate devices, Philips PageWriter TC20, TC30, TC50, TC70 (K191738).			

5.4 Device Description

PageWriter TC20, TC30, TC50, TC70 with VCG function – description of the device per 21 CFR 807.92(a) (4)

Philips Electrocardiograph, PageWriter TC cardiograph is a product family intended to acquire, record, display, analyze and store multi-channel ECG signals from adult and pediatric patients through a body surface ECG electrode. It includes PageWriter TC20, PageWriter TC30, PageWriter TC50 and PageWriter TC70. Each device under this product family is integrated with the algorithms to provide measurements, data presentations, graphical presentations and interpretations for review by the clinician on an advisory basis. The interpreted ECG with measurements and interpretive 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 TC cardiograph can be operated on the battery when the AC power cord or AC power connector is not in an operable condition, depending on the model of the cardiograph (TC20 - single battery only; TC30/TC50 - either one or two batteries; TC70 - two batteries only). When operating a PageWriter TC cardiograph with one battery or two, only the approved batteries with the same part number can be used.

PageWriter TC cardiograph has various configuration provided for the preference of the user, and can be updated with the compatible options/modules from the corresponding Upgrade Kit for use with all approved accessories and spare parts, including patient data cables, Patient Information Modules (PIM), lead sets, electrodes, print papers and trolleys. None of the accessories and spare parts are provided sterile.

Once configured, PageWriter TC cardiograph can provide integrated connectivity (wired or wireless) with the compatible Philips IntelliSpace ECG Management System, or other third party ECG system, for patient order download and ECG transmission. It also supports integrated connectivity with an ADT Order Update system to manage the patient demographic data, and transmit ECG reports in compliance with DICOM protocol once configured with DICOM option.

MODIFICATIONS

The modification to the subject devices was to provide a configurable report, vectorcardiogram (VCG) report in addition to the cleared 12-Lead Auto ECG reports. The VCG data (derived Frank lead signals for a single representative beat) is from an existing DXL 12/16-Lead ECG algorithm to provide three-dimensional signals X, Y, and Z (Frank leads) on vector angle (in degree) and vector magnitude (in mV). The cardiograph turns those signals into vector loops for the frontal plane (X,Y), the horizontal plane (X,Z) and the sagittal plane (Y,Z). The ability of the cardiograph to render and present the VCG report was done by collating VCG data and printing to the final ECG report through Cardiograph Report Manager Module under Business Logic Layer.

5.5 Indications for Use

Intended Use as required per 21 CFR 807.92(a)(5)

Philips Electrocardiograph, PageWriter TC cardiograph (TC20, TC30, TC50, and TC70) 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.

5.6 Comparison of Intended Uses for Subject Device and Predicate

The intended use for the subject devices and the predicates is identical.

The Indication for Use statement for PageWriter TC20, TC30, TC50, and TC70 with the proposed software version is identical to the predicates. There is no change to the indication for use statement in this submission.

5.7 Comparison of Technological Characteristics with the Predicate Device

Similarities

Philips Electrocardiograph, PageWriter TC20, TC30, TC50, TC70 with the proposed modifications VCG report has similar technological and performance characteristics as the predicate devices cleared under K191738.

It is intended to acquire, record, display, analyze, store and print the multi-channel ECG signals from adult and pediatric patients through a body surface ECG electrode. It is integrated with algorithm that provide measurements, data presentations, graphical presentations and interpretations for review by the clinician on an advisory basis. The basic technological and performance characteristics are kept same for the subject devices with the proposed modifications and the predicates.

- ECG Acquisition
- ECG Quality Monitor
- ECG Memory and Transfer
- ECG Interpretation
- Print Preview Capability
- Clinical Workflow – Networked Orders

Differences

The cardiographs with the proposed modification provide a configurable report presentation, VCG report, in addition to the existing 12-Lead Auto ECG reports. Display formats presented by the existing ECG reports are not changed as the result of the proposed modification.

The VCG data (derived Frank lead signals for a single representative beat) is a part of DXL algorithm outputs that was cleared in DXL 12/16-Lead ECG Algorithms (K052049, K073376, K132068) and presented in three-dimensional signals X, Y, and Z (Frank leads) on vector angle (in degree) and vector magnitude (in mV). The cardiograph turns those signals into vector loops for the frontal plane (X,Y), the horizontal plane (X,Z) and the sagittal plane (Y,Z). The ability of the cardiographs to render and present the VCG report was done by collating VCG data from DXL algorithm and printing to final ECG report through Cardiograph Report Manager Module under Business Logic Layer. Final presentation of VCG is an additional page to auto ECG reports.

5.8 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety, Electromagnetic Compatibility (EMC) and Usability

The change was evaluated for impact on electrical safety, electromagnetic compatibility (EMC) and usability according to the consensus standards, and determined that the proposed modification, the addition of vectorcardiograph report did not require additional testing. PageWriter TC20, TC30, TC50, TC70 with VCG function are in compliance with the consensus standards, including IEC 60601-1, IEC 60601-2-25, IEC 60601-1-2 and IEC 62366-1.

Software and Cybersecurity

The change to the software was reviewed through risk management process and determined that software functional testing was required. The testing was needed to verify the ability of the cardiographs to present VCG report, and to ensure the presented vectorcardiograph (VCG) loop is in the correct direction (rotation) and has the accurate magnitude. PageWriter TC20, TC30, TC50, TC70 with VCG function was developed in compliance with IEC 62304:2006/A1:2015. The proposed change did not impact the effectiveness of the security measures in place to the subject devices.

No other functions of the subject devices were impacted by the proposed changes. No other performance data is required as a result of this modification.

5.9 Clinical Studies

This premarket submission did not require clinical study to demonstrate the substantial equivalence.

5.10 Conclusions

The verification and validation demonstrate that the **PageWriter TC20, TC30, TC50, TC70 with VCG function** is substantially equivalent to the predicate PageWriter TC20, TC30, TC50 and TC70 cleared through K191738. The fundamental technology and intended use of the subject devices have not changed. The proposed change, the addition of vectorcardiograph (VCG) report is presented in a VCG loop with a correct direction and an accurate magnitude, which does not raise different questions of safety and effectiveness to the subject devices when compared to the predicates. The subject devices can operate as intended.