September 29, 2020

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

Re: K191738
Trade/Device Name: PageWriter TC20, TC30, TC50, TC70
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: September 29, 2019
Received: October 2, 2019

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,

for

Jennifer Shih
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191738

Device Name

Philips Electrocardiograph PagerWriter TC20, TC30, TC50, TC70

Indications for Use *(Describe)*

Phillips Electrocardiograph PageWriter TC cardiograph (TC20, TC30, TC50, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

I. SUBMITTER

Philips Healthcare-VSS-Shanghai CDC
A division of Philips Medical Systems
Building A2, #718 Lingshi Road, Jingan District,
Shanghai, China 200072

Contact: Hong Zhu
Sr. Regulatory Affairs Manager
Telephone: +86 18501616553
Email: hong.zhu_2@philips.com

Dated Prepared: August 18, 2020

II. DEVICE

Trade Name:	PageWriter TC20, TC30, TC50, TC70
Common Name:	Cardiograph
Catalogue Number:	TC20 (860332), TC30 (860306), TC50 (860310), TC70 (860315)
Classification Name:	Electrocardiograph
Class/Regulation:	Class II, 21 CFR § 878.2340
Product Code:	DPS

III. PREDICATE DEVICE

Philips PageWriter TC20, TC30, TC50, TC70

- K113144 (cleared 4/3/2012 for TC20)
- K080999 (cleared 5/9/2008 for TC30, TC50, TC70)

The devices are subject to a firm-initiated recall due to the over-heat of the battery when used beyond the end of the battery's life. This 510(k) Notification is to address the battery life.

IV. DEVICE DESCRIPTION

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. The cybersecurity on PageWriter TC cardiograph is periodically and proactively improved according to the cybersecurity analysis and the routine device cyber maintenance plan.

MODIFICATIONS

This bundled Traditional 510(k) Notification proposes the device modification under software A.07.07 to PageWriter TC cardiograph family, PageWriter TC20, TC30, TC50, and TC70 under the same intended use and indication for use statement.

The modifications under software A.07.07 will provide incremental improvements on the battery lifecycle management while maintaining the same basic functionality and intended use. The design improvements related to battery management are common to all cardiographs and listed below.

- Battery overcharge protection
- Battery overheating protection
- Battery lifecycle management
- Battery abnormality reporting and logging
- Updates to labeling including re-phrasing and relocation of precautions and warnings

The proposed modifications under software A.07.07 also include the design enhancement for the purpose of remote service maintenance and post-market cybersecurity.

V. INDICATIONS FOR USE

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.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH TH PREDICATE DEVICE

Philips Electrocardiograph, PageWriter TC20, TC30, TC50, TC70 with the proposed modifications under software A.07.07 has similar technological and performance characteristics as the predicate devices cleared under K113144 and K080999.

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
- Display Formats

The cardiographs with the proposed change under software A.07.07 provides incremental improvements over the predicates regarding the battery lifecycle management while maintaining the same basic functionality and intended use. These improvements are summarized below, including the labeling update.

- Battery overcharge protection
- Battery overheating protection
- Battery lifecycle management
- Battery abnormality reporting and logging
- Updates to labeling including re-phrasing and relocation of precautions and warnings

The proposed change under software A.07.07 also provides the enhancements for the subject devices to perform service maintenance remotely and to improve the post market cybersecurity.

VII. PERFORMANCE DATA

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

Electrical safety, Electromagnetic Compatibility (EMC) and Usability

The changes were evaluated for impact on electrical safety, electromagnetic compatibility (EMC) and usability according to the consensus standards and determined that the proposed changes on the battery lifecycle management did not require additional electrical safety, EMC and usability testing. PageWriter TC20, TC30, TC50, TC70 cardiographs continue meeting the requirements of those consensus standards, including IEC 60601-1, IEC 60601-2-25, IEC 60601-1-2 and IEC 62366-1.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documented as provided in according with *FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* and *IEC 62304:2006/A1:2015, Medical Device Software – Software Life Cycle Processes.* The software for the subject device was considered as a "moderate" level of concern, since the modified software would not directly result in serious injury or death to the patient or operator.

Cybersecurity

Cybersecurity testing was conducted and documented for the proposed change in accordance with FDA's *Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, and demonstrated an effective cybersecurity is in place to assure the device functionality and safety. The enhancement made for the service purpose and post market cybersecurity does not raise the new questions of safety and effectiveness.

Battery and Functional Testing

The battery was qualified through testing at the part level and the system level when integrated into the host device according to the applicable industry and FDA consensus standards. System verification testing showed that each device under PageWriter TC cardiograph family meets all required functionality including the battery lifecycle management and meets its system specifications as it's intended.

Clinical Studies

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

VIII. CONCLUSIONS

The verification and validation activities demonstrate that Philips Electrocardiograph, PageWriter TC20, TC30, TC50, TC70 with software A.07.07 is substantial equivalent to the predicate PageWriter TC20, TC30, TC50 and TC70 cleared through K113144 and K080999.

The fundamental technology and intended use of PageWriter TC20, TC30, TC50, TC70 cardiographs has not changed. Moreover, the results of testing demonstrate that the device modifications under software A.07.07 do not raise the new question of the safety or performance of the cardiographs.