May 5, 2025

Philips Medizin Systeme Böblingen GmbH
Mary Couch
Sr. Regulatory Affairs Specialist
Hewlett-Packard Strasse 2
Böblingen, BW 71034
Germany

Re: K242962
Trade/Device Name: Telemetry Monitor 5500 Release 4.0 (867232)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DQA, DRG, DRT, DRW, DSA, DSI, MLD, MSX
Dated: September 25, 2024
Received: April 3, 2025

Dear Mary Couch:

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.

510(k) Number *(if known)*
K242962

Device Name
Telemetry Monitor 5500 Release 4.0 (867232)

Indications for Use *(Describe)*
Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals.

Not intended for home use. Intended for use by health care professionals.

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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"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."

510(k) Summary

1.1 Submitter

Date Prepared: 20 September 2024

Submitter/Owner: Philips Medizin Systeme Böblingen GmbH
FDA Establishment Number 9610816
Hewlett-Packard-Str. 2
71034 Böblingen
Germany

Key Contact: Mary Couch, Sr. Regulatory Affairs Specialist
mary.couch@philips.com

510(k) Submission Type: Traditional 510(k)

1.2 Device Name and Classification

Trade Name (Part Number): Telemetry Monitor 5500 Release 4.0 (867232)

Common Name: Telemetry Patient Worn Monitor

Classification Name: 21 CFR §870.1025

Regulatory Class: Class II

Primary Product Code: MHX – Monitor, physiological, patient (with arrhythmia detection or alarms)

Subsequent Product Codes:

Product Code	Regulation number/Device
DQA	21 CFR 870.2700 Oximeter.
DRW	21 CFR 870.2350 Electrocardiograph lead switching adaptor.
DSA	21 CFR 870.2900 Patient transducer and electrode cable (including connector).
MSX, DRT	21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).
DRG	21 CFR 870.2910 Radiofrequency physiological signal transmitter and receiver.
DSI, MLD	21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

1.3 Predicate Device

The subject device is substantially equivalent to the legally marketed predicate device:

510(k) Number	Device Name	Primary Product Code	Company
K180017	MX40 Release C.01	MHX	Philips Medical Systems 3000 Minuteman Road Andover, MA 01810

1.4 Device Description

The Telemetry Monitor 5500 is a battery-operated patient worn monitor with a touchscreen display. The Telemetry Monitor 5500 is intended to monitor and record, and to generate alarms for, multiple physiological parameters like ECG, SpO2, and respiration rate. It is equipped with a 1.4 GHz radio to enable wireless bi-directional data flow with Philips' Patient Information Center (PIC) iX.

1.5 Intended Use and Indication for Use

Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.

1.6 Comparison of Intended Uses for Subject Device and Predicate

The Telemetry Monitor 5500 has the same intended use and indications as the legally marketed predicate device.

1.7 Comparison of Technological Characteristics with Predicate Device

Specification	Predicate Device IntelliVue MX40 Release C.01 (K180017)	Subject Device Telemetry Monitor 5500 Release 4.0	Comparison
Intended Use/ Indications for Use	Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.	Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in a hospital environment and during patient transport inside hospitals. Not intended for home use. Intended for use by health care professionals.	Identical.
Contraindications	There are no contraindications for use of the MX40.	The Telemetry Monitor 5500 is contraindicated for use with	Substantially equivalent.

Specification	Predicate Device IntelliVue MX40 Release C.01 (K180017)	Subject Device Telemetry Monitor 5500 Release 4.0	Comparison
		infants and neonates.	The subject device has updated the restrictions articulated in the predicate device's Patient Population statement and explicitly made it a contraindication. This aligns with the predicate device's patient population which is the same.
Patient population	Adults and pediatrics. (This device is not for use with infant or neonatal patients.)	Adult and Pediatric (Child and Adolescent[1]). Not for use with infants or neonatal patients. [1] The US Food and Drug Administration defines pediatric subpopulations as: Children – 2 years to less than 12 years old, and Adolescents - aged 12 through 21.	Identical.
Physiological Parameters Monitored	• ECG • Respiratory Rate • SpO_2	• ECG • Respiratory Rate • SpO_2	Identical.
ECG Accessories	• Foam electrodes • Solid gel electrodes • Snap electrodes • Leadsets • Patient cables	• Foam electrodes • Solid gel electrodes • Snap electrodes • Leadsets • Patient cables	Identical.
ECG and Arrhythmia Monitoring	Uses Philips proprietary monitoring algorithms for ECG arrythmia monitoring. • EASI • Hexad • ST/AR Arrhythmia Monitoring • ST/AR ST Analysis Algorithm • ST/AR QT/QTc Interval Monitoring	Uses Philips proprietary monitoring algorithms for ECG arrythmia monitoring. • EASI • Hexad • ST/AR Arrhythmia Monitoring • ST/AR ST Analysis Algorithm • ST/AR QT/QTc Interval Monitoring	Identical.
ECG information	Up to two (2) waves can be visualized at any given time. User can sort through and see all available ECG waves but only two (2) at a time.	Offers a multi-lead screen as a scrollable screen that shows all available ECG waves in a single screen.	Substantially equivalent. The multi-lead view makes information more readily accessible for the user, but the same information is available when using the predicate device.
SpO_2 Accessories	• Philips FAST disposable/ reusable SpO2 sensors • Masimo disposable/reusable SpO2 sensors • Medtronic Nellcor disposable/reusable SpO2 sensors	• Philips FAST disposable/ reusable SpO2 sensors • Masimo disposable/reusable SpO2 sensors	Identical. (The subject device does not introduce any new SpO2 accessories. The fact that the subject device does not use Nellcor accessories does not alter the performance of the subject

Specification	Predicate Device IntelliVue MX40 Release C.01 (K180017)	Subject Device Telemetry Monitor 5500 Release 4.0	Comparison
			device (i.e., SpO_2 monitoring) which is identical relative to the predicate device.)
SpO2 Performance Specifications	Accuracy claims (results) are sensor specific and range between ± 1-3 % for measurements between 70-100 % SpO2.	Accuracy claims (results) are sensor specific and range between ± 1-3 % for measurements between 70-100 % SpO2.	Identical.
Dimensions	Height 126.8 mm (4.99 in) *excluding patient cable connector port* Width 69.9 mm (2.75 in) Depth 31.5 mm (1.24 in)	Height 138 mm (5.43 in) Width 70 mm (2.75 in) Depth 25 mm (0.98 in)	Substantially equivalent No significant change in size relative to the predicate device. The exact dimensions of the subject device do not affect the operation.
User Interface			Substantially equivalent. There is no change in user workflow or tasks performed by the user. The graphical user interface has been updated in minor ways, e.g., the patient's name is displayed closer to the physiological data, and the wireless icon now indicates the status of the device's connection to PIC iX (as opposed to whether a connection with a Smart-hopping Access Point is established). The physical aspects of the subject device's user interface are largely identical. Some features that are no longer present in the subject device do not affect the intended use of the device. For example, the membrane button in the predicate device has been eliminated. Summative usability testing has shown that the performance of the subject device does not raise questions of safety and effectiveness relative to the predicate device.
Battery Door Design	1. Battery Door (hinged) used with Lithium-ion battery, or:	1. Lithium-ion battery, or: 2. AA Battery Door (hinged)	Substantially equivalent.

Specification	Predicate Device IntelliVue MX40 Release C.01 (K180017)	Subject Device Telemetry Monitor 5500 Release 4.0	Comparison
	2. Battery Door (hinged) with Battery Tray and AA Batteries	with AA Batteries	The subject device design has been simplified by eliminating the use of one of the components that attaches batteries ("Battery Door"). Unlike the predicate device, the subject device's Lithium-ion battery does not need the Battery Door to be inserted and engaged into the device. When using AA Batteries, only the AA Battery Door needs to be used to insert and engage the batteries in the device. The design of the subject device, including this feature, has been validated as part of usability testing.
Sterilization/ Cleaning	Non-sterile device, reusable. Clean and disinfect (70% Isopropyl Alcohol).	Non-sterile device, reusable. Clean and disinfect (70% Isopropyl Alcohol).	Identical.
Energy Source	Powered by rechargeable Lithium-Ion battery or three (3) AA batteries	Powered by rechargeable Lithium-Ion battery or three (3) AA batteries	Identical.
Battery Life	**Lithium Ion Battery:** ECG Only: 9-30 hours (depending on Device Mode and display settings) ECG/SpO2 FAST Continuous: 7-15.6 hours **AA Batteries:** ECG only: 6.8-37 hours (depending on Device Mode and display settings) ECG/SpO2 FAST Continuous: 4.7-22 hours	**Lithium Ion Battery:** ECG only: 8-31 hours (depending on Device Mode and display settings) ECG/SpO2 FAST Continuous: 7-20 hours **AA Batteries:** ECG only (depending on Device Mode and display settings): 9-46 hours ECG/SpO2 FAST Continuous: 4-24 hours	Substantially equivalent. The subject device has an improved battery life (also known as runtime). There is no change in the battery technology or power source. There are no new risks being introduced by increased battery life.
Speaker	Magnetic coil-actuated speaker.	Magnetic coil-actuated speaker.	Substantially equivalent. The assembly in the subject device integrates an acoustic back volume as an improvement over the predicate device.
Wireless Communication (Hardware)	Main radio technology: • WMTS 1.4 GHz radio 1.0 Supplementary radio technology: • IEEE 802.15.4 radio (sometimes referred to as a "short range radio")	Main radio technology: • WMTS 1.4 GHz radio 2.0 Supplementary radio technology: • Bluetooth Low Energy (BLE) radio (Note: BLE functionality is not yet	Substantially Equivalent. As with the predicate device, the subject devices uses wireless communication is used to configure device settings (including alarm limits). In both

Specification	Predicate Device IntelliVue MX40 Release C.01 (K180017)	Subject Device Telemetry Monitor 5500 Release 4.0	Comparison
		enabled.)	cases, the hardware that enables wireless communication is the WMTS 1.4 GHz radio. The absence of an IEEE 802.15.4 radio in the subject device does not change the intended use or affect the substantial equivalence of the subject device.
Cybersecurity	Does not support end-to-end data encryption and authentication in telemetry installation.	Supports end-to-end data encryption and authentication in telemetry installation using Smart-hopping 2.0 (default setting). May also support unencrypted legacy telemetry installations using Smart-hopping 1.0 ("compatibility mode").	Substantially Equivalent Unlike the predicate device, the subject device enables and supports end-to-end encryption and authentication with a compatible version of the central station, PIC iX. The enhanced technological characteristics of the subject device's WMTS 1.4 GHz radio do not raise concerns about clinical performance. This change is made to strengthen cybersecurity and achieve a higher degree of protection of sensitive information.

1.8 Substantial Equivalence Summary

The Telemetry Monitor 5500 shares the same operating principle, clinical performance, overall design, and technological characteristics as the predicate device (K180017). The Telemetry Monitor 5500 also has the same intended use/indications as the predicate device and uses the same packaging materials and cleaning method/protocol. Minor updates to the Telemetry Monitor 5500 do not change the fundamental scientific technology of the cleared device which is shared by the Telemetry Monitor 5500. Minor differences from the predicate device are limited to the following aspects:

- Updates to the user interface. The Telemetry Monitor 5500 exterior design has been modernized and the subject device's graphical user interface has updated how some information is presented. There is no change in how physiological parameters or alarms are displayed. There is no change in user workflow or tasks performed by the user.
- Increased battery runtime due to improvements in technology. There is no change in the energy source used (battery-powered).
- End-to-end data encryption and authentication are supported by the Telemetry Monitor 5500 via Smart-hopping 2.0 (default setting). The device also continues to support unencrypted data transfers via Smart-hopping 1.0 (compatibility mode). There is no change to the wireless communication method.

These changes do not raise any questions about the safety and effectiveness of the Telemetry Monitor 5500 as compared to the predicate device.

1.9 Performance Data

1.9.1 Non-Clinical Tests

Electrical Safety and Electromagnetic Compatibility (EMC)

The Telemetry Monitor 5500 was assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD1:2021] IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Performance Testing

Functional and system level testing of the Telemetry Monitor 5500 was performed. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]/IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ANSI AAMI IEC 60601-2-27:2011(R) 2016/IEC 60601-2-27:2011-03 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-49 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Software Testing

Development and testing of the Telemetry Monitor 5500 embedded software was conducted in accordance with ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes and FDA's Guidance for Industry and Food and Drug Administration Staff, "Content of Premarket Submissions for Device Software Functions" (June 14, 2023).

1.9.2 Clinical Studies

Philips conducted clinical studies in accordance with FDA Guidance Document "Pulse Oximeters – Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff" (March 4, 2013), as well as ISO 80601-2-61:2017, to support accuracy performance. Results show that the Telemetry Monitor 5500 meets the acceptance criteria laid out in the associated protocols.

1.10 Conclusion

The results of the comparison to the predicate device, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification, usability testing, and clinical performance demonstrate that the Telemetry Monitor 5500 is substantially equivalent to the predicate device.