January 17, 2025

Philips Medizin Systeme Böblingen GmbH
Namita Nandurkar
Regulatory Affairs Specialist
Hewlett-Packard-Str. 2
Böblingen, BW 71034
Germany

Re: K243545

Trade/Device Name: Philips Reusable ECG Lead Sets and Trunk Cables : Model Number,Model Name: 989803170171, OR 3-Lead ECG Trunk Cable, AAMI/IEC; 989803170181, OR 5-Lead ECG Trunk Cable, AAMI/IEC; M1667A, 6 Lead ECG Trunk, AAMI/IEC 2.7m; M1668A,5 Lead ECG Trunk, AAMI/IEC 2.7m; M1669A,3 Lead ECG Trunk, AAMI/IEC 2.7m; M1949A,5+5 ECG Trunk cable AAMI, IEC 2.7m; M1663A,10 Lead ECG Trunk AAMI/IEC 2m; M1665A, 6+4 Lead ECG Trunk AAMI/IEC 2.7m; M1671A, 3 Leadset, Grabber, AAMI, ICU; M1673A, 3 Leadset, Snap, AAMI, ICU; M1675A, 3 Leadset, Grabber, AAMI, OR; M1624A, Unshielded 3 Ld Miniclip AAMI; M1532A, 4 Lead Set Grabber AAMI, ICU; M1968A, 5 Leadset, Grabber, AAMI, ICU; M1644A, 5 Leadset, Snap, AAMI, ICU; M1973A, 5 Leadset, Grabber, AAMI, OR; M1976A, 5 Leadset, Grabber, Chest, AAMI, ICU; M1602A, 5 Lead Snap Chest AAMI, ICU; M1979A, 5 Leadset, Grabber, Chest, AAMI, OR; M1680A, 6 Lead Set Grabber AAMI, ICU

Regulation Number: 21 CFR 870.2900

Regulation Name: Patient Transducer And Electrode Cable (Including Connector)

Regulatory Class: Class II

Product Code: DSA

Dated: July 19, 2024

Received: November 15, 2024

Dear Namita Nandurkar:

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)*

K243545

Device Name

Philips Reusable ECG Lead Sets and Trunk Cables :
Model Number,Model Name:
989803170171, OR 3-Lead ECG Trunk Cable, AAMI/IEC;

989803170181, OR 5-Lead ECG Trunk Cable, AAMI/IEC;

M1667A, 6 Lead ECG Trunk, AAMI/IEC 2.7m;

M1668A,5 Lead ECG Trunk, AAMI/IEC 2.7m;

M1669A,3 Lead ECG Trunk, AAMI/IEC 2.7m;

M1949A,5+5 ECG Trunk cable AAMI, IEC 2.7m;

M1663A,10 Lead ECG Trunk AAMI/IEC 2m;

M1665A, 6+4 Lead ECG Trunk AAMI/IEC 2.7m;

M1671A, 3 Leadset, Grabber, AAMI, ICU;

M1673A, 3 Leadset, Snap, AAMI, ICU;

M1675A, 3 Leadset, Grabber, AAMI, OR;

M1624A, Unshielded 3 Ld Miniclip AAMI;

M1532A, 4 Lead Set Grabber AAMI, ICU;

M1968A, 5 Leadset, Grabber, AAMI, ICU;

M1644A, 5 Leadset, Snap, AAMI, ICU;

M1973A, 5 Leadset, Grabber, AAMI, OR;

M1976A, 5 Leadset, Grabber, Chest, AAMI, ICU;

M1602A, 5 Lead Snap Chest AAMI, ICU;

M1979A, 5 Leadset, Grabber, Chest, AAMI, OR;

M1680A, 6 Lead Set Grabber AAMI, ICU

Indications for Use *(Describe)*

Philips IntelliVue reusable ECG lead sets/trunk cables and Philips OR ECG trunk cables are

indicated for continuous monitoring of cardiac signals for both diagnostic and monitoring purposes. These devices are limited by the indications for use of the connected monitoring and diagnostic equipment in healthcare facilities. These devices are intended to interact with patient intact skin only.

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."

510(k) Summary

510(k) Summary

Submitter

Date Prepared	October 29, 2024
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany
Key Contact	Namita Nandurkar Regulatory Affairs Specialist namita.nandurkar@philips.com Phone: +49 17668210269
510(k) Submission Type	This is a traditional 510(k).

Device

Trade Name	Philips Reusable ECG Lead Sets and Trunk Cables
Common Name	ECG Cables and Lead Sets
Classification Name	Panel & Name: Cardiovascular Devices Subpart & Division: 21 CFR §870.2900 Regulatory Class: II Product Code: DSA

Predicate Device and Reference Device

	510(k) No.	***Company***	***Device Name***	***Product Code***
Predicate Device	K181726	Medline Industries, Inc	Medline Patient Cables and Lead Wires	DSA
Reference Device	K211294	Vyaire Medical, Inc.	Multi-Link X2 ECG Cable and Lead wire System	DSA

The subject devices are substantially equivalent to the legally marketed predicate devices.

Device Description

Philips Reusable ECG Lead Sets and Trunk Cables – description of the device per 21 CFR 807.92(a) (4)

Philips Reusable ECG Lead Sets and Trunk Cables are non-sterile and non-invasive reusable medical devices designed to transfer ECG signals from the patient to the monitor used in the healthcare facilities, which includes intensive care unit (ICU) for both adults and neonates and the operating room (OR). The ECG cables and lead sets are used to forward an electrical cardiac signal via electrical wires from the electrode attached on patient skin to the ECG measurement hardware in the patient monitor and to support other outputs as needed. The portfolio consists of two types of trunk cables and two types of lead sets: ICU and OR, including various electrode connectors with AAMI and IEC coloring. The ECG Trunk cables and lead sets are suitable for multiple patient use. The Philips Reusable ECG Lead Sets and Trunk Cables have a service life of 18 months. The Philips Reusable ECG Lead Sets and Trunk Cables can be used with any Philips monitors including Philips monitor/defibrillator product lines and Philips monitoring or diagnostic equipment which claim compatibility to Philips Reusable ECG Lead Sets and Trunk Cables.

Intended Use and Indication for Use

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

Intended Use:
Philips IntelliVue Reusable ECG lead sets and trunk cables are limited by the indications for use of the connected monitoring and diagnostic equipment and are for use only by healthcare professionals. They are designed for multiple patient use and indicated for monitoring cardiac signals for both diagnostic and monitoring purposes in adult, pediatric, and neonatal patients. Philips operating room (OR) ECG trunk cables are indicated for use to monitor patient ECG in an electrosurgery (ESU) environment when used in combination with a compatible ECG patient lead set on adult, pediatric, infant, and neonatal ECG applications.

Indications for Use:
Philips IntelliVue reusable ECG lead sets/trunk cables and Philips OR ECG trunk cables are indicated for continuous monitoring of cardiac signals for both diagnostic and monitoring purposes. These devices are limited by the indications for use of the connected monitoring and diagnostic equipment in healthcare facilities. These devices are intended to interact with patient intact skin only.

Comparison of Intended Uses for Subject Device and Predicate

The intended use of the subject device is worded slightly differently from that of the predicate device, but they serve the same general purpose based on the following points:

- **Connection to Monitoring and Diagnostic Equipment:** Both the subject and predicate devices are designed to connect to patient monitoring systems, ensuring secure and reliable signal transmission.
- **Usage by Healthcare Professionals:** Both devices are used exclusively by healthcare professionals in clinical settings.
- **Intended for Monitoring and Diagnostic Purposes:** Both devices are intended solely for monitoring and diagnostic purposes, facilitating the evaluation of patient health.

The subject and predicate devices are considered accessories, as defined by the FDA. An accessory is a finished device intended to support, supplement, and/or augment the performance of one or more parent devices. These devices support the performance of parent devices by enabling or facilitating those devices to perform according to their intended use. Both the subject and predicate devices function as accessories to patient monitoring systems by providing reliable connections between the patient and the monitoring/diagnostic equipment. Therefore, the subject device's general purpose and intended use are identical to the predicate device.

- **Subject Device Intended Use:** Philips IntelliVue reusable ECG lead sets and trunk cables are limited by the indications for use of the connected monitoring and diagnostic equipment and are for use only by healthcare professionals. They are designed for multiple patient use and indicated for monitoring cardiac signals for both diagnostic and monitoring purposes in adult, pediatric, and neonatal patients. Philips operating room (OR) ECG trunk cables are indicated for use to monitor patient ECG in an electrosurgery (ESU) environment when used in combination with a compatible ECG patient lead set on adult, pediatric, infant and neonatal ECG applications.
- **Predicate Device Intended Use:** Medline Patient Cables and Lead Wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.

Comparison of Technological Characteristics with Predicate Device	
Similarities	
Item of Comparison	**Description/Rationale**
Indications for Use	The indications for use are worded slightly differently but are essentially identical based on the following points: • Both devices are connected to electrodes to monitor and diagnose electrocardiogram (ECG) signals. • Both devices are connected to monitoring and diagnostic equipment. • The general purpose and intended use of the subject and predicate devices are identical. The indications for use for both the subject and predicate devices are worded differently, but both are ultimately limited by the indications for the use of the connected monitoring or diagnostic equipment that monitors the patient's ECG. • **Subject Device Indications for Use**: Philips IntelliVue reusable ECG lead sets/trunk cables and Philips OR ECG trunk cables are indicated for continuous monitoring of cardiac signals for both diagnostic and monitoring purposes. These devices are limited by the indications for use of the connected monitoring and diagnostic equipment in healthcare facilities. These devices are intended to interact with patient intact skin only. • **Predicate Device Indications for Use:** Medline Patient Cables and Lead Wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional. Additionally, the use of Medline Patient Cables and Lead Wires is limited by the indications for use of the ECG monitoring or diagnostic equipment it is connected to. Medline Patient Cables and Lead Wires are intended for Prescription Use only.
Principle of Operation	Subject and Predicate Devices emphasize that the operation of the device is confined to the area from the patient electrodes to the monitoring/diagnostic equipment, providing a means of cable connection for ECG signal transmission. Therefore, the subject and predicate device are identical.
Patient Population	The patient populations between the subject and predicate device are worded slightly differently, but they encompass the same patient groups, which are Adult and pediatric. Therefore, the subject and predicate device are identical.

Anatomical Sites	The operational and functional characteristics of the subject and predicate devices are identical, as they both attach to the exact body locations, which are Left arm, Right arm, Chest, Left leg & Right leg and serve the same purpose. Therefore, the subject and predicate device are identical.
Environment of Use	The subject device (healthcare facility) and predicate device (healthcare settings) are used in identical environments. Therefore, the subject and predicate device are identical.
Sterility	The subject device is identical to the predicate device, as both have nonsterile trunk cables and lead sets. Since neither device requires sterility, they are identical.
Prescription Use	The subject and predicate devices are for prescription use and intended for use in identical environments. Therefore, are identical.
Differences	
Number of Lead wires in a Lead Set	The subject device includes 4 and 6 lead wire lead sets which is not seen in the predicate device (includes 3 and 5 lead wire lead sets). This difference does not raise different questions of safety and effectiveness.

Reusability	The subject device is substantially equivalent to the predicate device based on the following points: • The subject device has reusable lead sets, while the predicate has disposable lead sets. This difference does not raise different questions of safety and effectiveness because the core function of transmitting ECG signals remains unchanged, and both devices are designed to ensure signal transmission. The materials and design of the reusable lead sets meet rigorous standards for durability and hygiene, ensuring they can be safely reprocessed and reused. • The subject device adheres to standards such as ISO 17664-2:2021, AAMI TIR12 (2020)/(R)2023, and ANSI AAMI ST98:2022. Additionally, it complies with the *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"* document issued by the FDA on March 17, 2015. • The proposed reprocessing instructions for the subject device are as effective as the predicate device. The subject device labeling meets all regulatory requirements and addresses any concerns related to reprocessing instructions for reusable devices. These instructions are consistent with state-of-the-art science to ensure the device is clean and disinfected. Therefore, despite the difference in reusability, the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.

Type of Lead set electrode connector	The subject device, featuring lead wires with Grabber, Snap, and Mini clip connectors, is substantially equivalent to the predicate device, which utilizes Pinch and Snap connectors. **Purpose:** Both devices connect patient electrodes to monitoring equipment, ensuring secure and reliable signal transmission. **Technological Characteristics:** • Subject Device: Connectors (Grabber, Snap, Mini clip), medical-grade materials, flexible design. • Predicate Device: Connectors (Pinch, Snap), medical-grade materials, flexible design. The Grabber and electrode Pinch have the same design but are named differently. The subject device includes a Mini clip, which is not present in the predicate device. The difference in the lead set electrode connector types is minor and does not raise different questions of safety and effectiveness, as performance testing addresses these differences. Therefore, the subject device is substantially equivalent to the predicate device.

Trunk cable to Monitor Connection	The subject device, featuring trunk cables with a 12-pin ECG connector for Philips monitors, is substantially equivalent to the predicate device, which uses 8-pin and 12-pin ECG connectors for Philips monitors. **Purpose:** Both devices connect trunk cables to Philips monitors, ensuring secure and reliable signal transmission for ECG monitoring. **Technological Characteristics:** Subject Device: 12-pin ECG connector. Predicate Device: 8-pin and 12-pin ECG connectors. The subject device does not offer an 8-pin connector. Compatibility with Philips monitors depends on specific monitor specifications. Both devices use similar materials and designs to ensure reliable connections. **Performance Characteristics:** Both devices meet standards for electrical conductivity, mechanical strength, and biocompatibility (ISO 10993-1). The subject device's absence of an 8-pin connector does not raise new questions of safety and effectiveness, this configuration is not offered in this submission. Performance testing confirms the trunk cables are safe and perform as intended for use with Philips monitors. Therefore, the subject device is substantially equivalent to the predicate device.
Lead Wire Construction	For neonate applications where the need for utmost cable flexibility exceeds a cable shield, Philips offers an unshielded 3-lead and 5-lead set. The monitor covers this case via respective measurement input circuits, allowing the desired ECG signal to pass but eliminating the disturbing rest. This illustrates the monitor's final, overarching responsibility since measurement accuracy is finally defined on the system level.
Performance Testing	The subject device complies with the same performance standards as the predicate device. Additionally, subject device **ICU** Lead Sets and Trunk cables also comply with additional performance standards i.e. IEC 60601-1-12.

Substantial Equivalence Summary

In accordance with 21 CFR Part 807, the Philips Reusable ECG Lead Sets and Trunk Cables are as safe and effective for their intended use as the Medline Patient Cables and Lead Wires (K181726). Both the predicate and reference devices share the same product code (DSA), ensuring similar FDA classification. As demonstrated in the sections above, the differences identified between the subject device and predicate device do not raise new questions of safety and effectiveness. Performance testing confirms that the Philips Reusable ECG Lead Sets and Trunk Cables are safe and performed as intended for Philips monitors.

The Medline Patient Cables and Lead Wires (K181726) serve as the predicate device, demonstrating the intended use of connecting patient electrodes to monitoring equipment and providing a basis for substantial equivalence comparison.
The Multi-Link X2 ECG Cable and Lead Wire System (K211294) serves as a reference device, supporting technological characteristics and further substantiating claims of equivalence.

Based on the above discussion, the differences in the technological characteristics of the subject and predicate devices do not raise new questions of safety and effectiveness. The subject device meets the predicate device's safety and performance standards. Additional performance standard (IEC 60601-1-12:2014 +AMD1:2020) met by the subject device's **ICU** Lead Sets and Trunk cables are identical to the one met by the reference device.

Performance Data

Non-Clinical Tests – Harmonized Standards

The subject devices have passed all safety tests for demonstrated compliance with the recognized standards below.

Standard	FDA Recognition #	Title #
IEC 60601-1:2005+A1:2012+A2:2020	19-49	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
ANSI AAMI EC53:2013/(R)2020	3-129	ECG trunk cables and patient lead wires
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 60601-2-27:2011(R)2016	3-126	Medical electrical equipment - Part 2-27: Particular

		requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
IEC 62366-1:2015+AMD1:2020:	5-129	Part 1: Application of usability engineering to medical devices

Non-clinical Bench Tests
No new issues of safety or effectiveness are introduced because of using this device.

Clinical Studies

The subject devices, like the primary predicate devices, did not require clinical trials.

Compliance to the FDA Quality System Regulations, FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, usability validation and risk management activities have taken place for the subject devices.

Based upon the design, intended use, indications for use, classification, usability and safety testing, the subject devices are substantially equivalent to the listed predicate devices.

No new issues of substantial equivalence are introduced as a result of using this device.

Conclusion

The results of the substantial equivalence assessment, taken together with non-clinical bench testing demonstrate that the subject devices do not raise different questions of safety and effectiveness when compared to the predicate, perform as intended, and have performance characteristics that are substantially equivalent to the predicate device.