August 6, 2025

Philips France Commercial
Sean Gibbons
Regulatory Affairs Manager
100 rue Reaumur
Paris, 75002
France

Re: K250569
Trade/Device Name: Cardiologs Holter Platform
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: July 7, 2025
Received: July 7, 2025

Dear Sean Gibbons:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250569

Please provide the device trade name(s).

Cardiologs Holter Platform

Please provide your Indications for Use below.

The Cardiologs Holter Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population.
The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices indicated for recording heart rhythm.
The Cardiologs Holter Platform can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system.
The Cardiologs Holter Platform provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement and rhythm analysis. The Cardiologs Holter Platform is not for use in life supporting or sustaining systems or ECG monitor and physiological alarm devices.
The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.
Cardiologs Holter Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250569

510(k) Summary

Prepared on: 2025-07-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Philips France Commercial
Applicant Address	100 rue Reaumur Paris 75002 France
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cardiologs Holter Platform
Common Name	Electrocardiograph
Classification Name	Electrocardiograph
Regulation Number	870.2340
Product Code(s)	DPS, DQK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212112	Cardiologs Holter Platform	DPS

Device Description Summary

21 CFR 807.92(a)(4)

Cardiologs Holter Platform is comprised of:
• An interface, which provides tools to measure, analyze and review numerous ECGs;
• An automated proprietary ECG interpretation support algorithm using artificial intelligence (AI) to analyze ECGs to provide clinicians with supportive information for ECG diagnosis.

Cardiologs Holter Platform is an online portal that can be accessed through a network connection and allows the clinician to review and annotate the ECG signals. Alternatively, the Cardiologs Holter Platform can be accessed via an Application Programming Interface (API) connection. The API connection allows a digital ECG upload from a connected device and allows the connected device to receive the output of the Cardiologs ECG interpretation support algorithm and further process and display its output in their system.

Cardiologs Holter Platform is intended to analyze recordings from devices used for the arrhythmia diagnostics such as Holter, event

recorder, 12 lead ambulatory ECG devices, or other similar devices for the assessment of heart rhythm in adult and pediatric populations.

Cardiologs Holter Platform works in the following way:
1. Upload of a digital ECG file to Cardiologs' secure hosting databases;
i. Manual upload: via the web-interface
ii. Direct upload: no manual intervention required, upload occurs whenever the third-party hardware or software system is connected to the Cardiologs' Application Programming Interface (or API) and the ECG is automatically sent to the Cardiologs' servers.

2. Processing of the uploaded ECG file;

3. Analysis and annotation of the uploaded ECG performed by Cardiologs' proprietary algorithm;

4. Display the analysis of the ECG, along with the original signal, to the clinician for review of patient data. The algorithm output may be accessed/displayed through the following interfaces:
i. The clinician can access the algorithm output directly within Cardiologs using Cardiologs' user interface.
ii. The clinician can access the algorithm output in their own downstream system. The downstream system receives the output of the algorithm via Cardiologs' Application Programming Interface (API).
The Cardiologs Holter Platform allows for editing and/or validation of the measurements and parameters by the analyzing clinician.

5. A PDF report is generated as the result of the analysis.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Cardiologs Holter Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population.
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Indications for Use Comparison 21 CFR 807.92(a)(5)

Equivalent; minor changes were made to the indications for use for clarity only, these changes do not result in a change to the product's use.

Technological Comparison 21 CFR 807.92(a)(6)

The modified device includes performance updates to enhance the accuracy of the currently cleared abnormalities and measurements and expanded pediatric indications. Both the predicate and proposed Cardiologs Holter Platform have similar indications for use, with minor changes to wording for clarification. In addition, they have substantially equivalence technological characteristics and performance specifications. Where there are differences, those differences do not raise different questions of safety or effectiveness. Performance testing demonstrates that the proposed device is as safe and effective and performs as well as the predicate. Based on this, Philips believes that the proposed Cardiologs Holter Platform is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The safety and performance of the subject device, the Cardiologs Holter Platform, has been evaluated and verified in accordance with its performance specifications and intended use to support a determination of substantial equivalence to the predicate device.

No clinical testing was performed in support of this premarket notification.

Performance testing demonstrates that the proposed device is as safe and effective and performs as well as the predicate. Based on this,

the proposed Cardiologs Holter Platform is substantially equivalent to the predicate device.