March 21, 2025

Philips Medizin Systeme Böblingen GmbH
Cathy Hong
Senior RA Specialist
Hewlett-Packard Strasse 2
Böblingen, 71034
Germany

Re: K241890
Trade/Device Name: Philips Holter Analysis System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO
Dated: May 31, 2024
Received: June 28, 2024

Dear Cathy Hong:

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,

Kimberly N. Crowley -S

Digitally signed by Kimberly N. Crowley -S

For: Jennifer Kozen
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K241890

Device Name
Philips Holter Analysis System

Indications for Use *(Describe)*

The Philips Holter Analysis System provides measurements, data, and reporting of parameters such as normal sinus rhythm, arrhythmias, QT and ST measurements, paced beats analysis and HRV, that can be used by a qualified clinician for the evaluation of:

- Symptoms that may be related to rhythm disturbances of the heart in adult patients
- Risk in patients with or without symptoms of arrhythmia. QT measurement information is provided to support this assessment by a competent health professional.
- Efficacy of antiarrhythmic therapy
- Pacemaker function
- Symptoms that may be associated with myocardial ischemia

The Philips Holter Analysis System is not intended for use for pediatric patients.

The EASI derived 12-lead ST measurements are not recommended unless patients meet the following parameters:

- Age: Between 33 to 82 years
- Height: Between 147 to 185 cm (58 to 73 inches)
- Weight: Between 53 to 118 kg (117 to 261 lbs)
- Height to Weight Ratio: Between 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

If patients do not meet these parameters, the EASI derived 12-lead ST measurements are not intended for use. EASI derived 12-Lead ECGs and their measurements are approximations to conventional 12-Lead ECGs and should not be used for diagnostic interpretations.

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.**

# *510(k) Summary*

| ***I. SUBMITTER*** | | | |
|---|---|---|---|
| **Date Prepared** | 20 March 2025 | | |
| **Submitter/Owner** | Company Name: Philips Medizin Systeme Böblingen GmbH<br>FDA Establishment Number: 9610816<br>Address: Hewlett-Packard Strasse 2, 71032 Böblingen, GERMANY<br>Phone: +1 (949)-502-1823 | | |
| **Key Contact** | Name: Cathy Hong<br>Title: Senior RA Specialist<br>Email Address: Cathy.HONG@philips.com | | |
| **510(k) Submission Type** | This is a Traditional 510(k) | | |
| II. ***DEVICE*** | | | |
| **Trade Name** | Philips Holter Analysis System | | |
| **Classification Name** | Panel & Name: Cardiovascular<br>Subpart & Division: Medical magnetic tape recorder<br>21 CFR: 21 CFR §870.2800<br>Regulatory Class: Class II<br>Product Code: MLO | | |
| ***III. PREDICATE DEVICE*** | | | |
| **Predicate Device** | ***510(k) No.*** | ***Company Name<br>Device Name*** | ***Product Code*** |
| | K010949 | 2010 Plus Holter for Windows | MLO |
| The Philips Holter Analysis System is substantially equivalent to the legally marketed predicate, 2010 Plus Holter for Windows (K010949). | | | |

## *IV. DEVICE DESCRIPTION*

The Philips Holter Analysis System (hereinafter known as Philips HAS) is offered as standalone software. It is intended to be installed into a user's PC (general purpose computing platform). The product evaluates the heart rhythms of ambulatory ECG data over an extended period and generates a preliminary analysis for physician's review. The ECG data is downloaded from compatible ambulatory ECG recorders. It is to be used by trained personnel.

The Philips Holter Analysis System accepts ECG recordings from DigiTrak XT recorders (K071733) and analyzes the patient's heart activity for the recorded period, typically from 24 hours up to 7 days. The

analysis is not performed in real time. The DigiTrak XT recorder collects up to 168 hours (7 days) of ambulatory ECG. The software can analyze up to 168 hours (7 days) of contiguous ECG data.

The algorithm (Zymed Algorithm, also internally referred to as the CAlg-Holter Algorithm) used in Holter Analysis System was first developed and approved for use in the Holter Scanner Model 1210. It was continually updated and subsequently cleared for use in more Holter Models. It includes Heart Rate Variability (Time Domain) as a standard software report configuration in March 1996. The operating system converted from a DOS operating system to a Windows operating system in April 1999. Heart Rate Variability Frequency Domain was added in February 2001. The QT analysis was added in September 2001. The most recent 510(k) including above features and functions is under K010949.

The Zymed Algorithm in the HAS incorporates the following enhancements in the subject device:

- Upgraded AFIB detection by replacing the current algorithm with the Philips ST/AR AFIB algorithm's P wave detection feature. The feature was cleared in K101521 with Philips ST/AR ST and Arrhythmia Software.
- Enhanced HRV reporting by replacing current calculations with advanced data warehouse calculations from PhysioNet. Incorporated Nonlinear HRV to provide more characterization of heart rate variability that linear methods could miss.
- Incorporated bug fix, and code security
- Upgraded compiler

The EASI derived 12-lead display function was cleared in K020456. It remains unchanged in the subject device. Philips does not incorporate any additional usage in the subject device beyond these clearances. The EASI 12-lead is only for display purposes, allowing end users to visualize EASI lead ECG recordings in a traditional 12-lead format. EASI derived 12-Lead ECGs and their measurements are approximations to conventional 12-Lead ECGs and should not be used for diagnostic interpretations.

No automatic functions or analyses utilize this data. The Zymed Algorithm performs its analysis on the raw ECG signal and does not use the EASI derived 12-lead in that analysis.

The Philips Holter Analysis System requires operator's intervention during and after the initial analysis. The Philips HAS allows the operator to view and print out an analysis report, individual heart rate strips, as well as a full disclosure report for physician's review, diagnoses, and observations. It is intended to assist the qualified medical professional in the interpretation of the recorded data; it is not intended to serve as a substitute for the review and overread of the recorded ECG data.

The Philips Holter Analysis System provides viewing, printing, and report export capabilities as listed below:

- A view of the data and a summary of the heart events that have taken place
- Detection of anomalies such as ventricular ectopy and supraventricular ectopy
- Patency of the pacemaker and pacemaker anomalies
- Advanced scanning techniques, such as determining ST and QT anomalies
- Heart rate data and heart rate variability
- Full disclosure reports

The Philips Holter Analysis System can operate in a networked environment that includes the following devices and interfaces to transfer orders and Holter reports.

- Philips IntelliVue Information Center (PIIC) (K153702)
- A fleet of Holter Remote Links and one or more Holter Central Links
- IntelliSpace ECG Management System (ISECG) (K120855)
- An IntelliBridge Enterprise (IBE) data interface engine / brokering system
- DICOM-based enterprise systems

PIIC , Holter Remote Links, and Holter Central Links provide alternate ECG input mechanisms for Holter analysis. ISECG Central Link, Report Viewer, and IBE can accept Holter reports. IBE can provide Orders and ADT information for HAS. DICOM-based systems support patient orders via DICOM Modality Worklist and accept exported DICOM Encapsulated PDF reports.

The Philips Holter Analysis System provides three models with different configurations for customers to select: Series 3000, Series 5000, and Series 7000.

## *V. INDICATIONS FOR USE*

The Philips Holter Analysis System provides measurements, data, and reporting of parameters such as normal sinus rhythm, arrhythmias, QT and ST measurements, paced beats analysis and HRV, that can be used by a qualified clinician for the evaluation of:

- Symptoms that may be related to rhythm disturbances of the heart in adult patients.
- Risk in patients with or without symptoms of arrhythmia. QT measurement information is provided to support this assessment by a competent health professional.
- Efficacy of antiarrhythmic therapy
- Pacemaker function
- Symptoms that may be associated with myocardial ischemia

The Philips Holter Analysis System is not intended for use for pediatric patients.

The EASI derived 12-lead ST measurements are not recommended unless patients meet the following parameters:

- Age: Between 33 to 82 years
- Height: Between 147 to 185 cm (58 to 73 inches )
- Weight: Between 53 to 118 kg (117 to 261 lbs)
- Height to Weight Ratio: Between 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)

If patients do not meet these parameters, the EASI derived 12-lead ST measurements are not intended for use. EASI derived 12-Lead ECGs and their measurements are approximations to conventional 12-Lead ECGs and should not be used for diagnostic interpretations.

## *VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE*

The following tables compare Philips Holter Analysis System to the predicate device with respect to indications for use and technological characteristics to provide information regarding the basis for the determination of substantial equivalence.

**Table 1-Comparison of Indications for Use**

| Item of Comparison | Philips Holter Analysis System (Subject Device) | 2010 Plus Holter for Windows (K010949) |
|---|---|---|
| Indications for Use | The Philips Holter Analysis System provides measurements, data, and reporting of parameters such as normal sinus rhythm, arrhythmias, QT and ST measurements, paced beats analysis and HRV, that can be used by a qualified clinician for the evaluation of:<br>• Symptoms that may be related to rhythm disturbances of the heart in adult patients<br>• Risk in patients with or without symptoms of arrhythmia. QT measurement information is provided to support this assessment by a competent health professional.<br>• Efficacy of antiarrhythmic therapy<br>• Pacemaker function<br>• Symptoms that may be associated with myocardial ischemia<br><br>The Philips Holter Analysis System is not intended for use for pediatric patients.<br><br>The EASI derived 12-lead ST measurements are not recommended unless patients meet the following parameters:<br>• Age: Between 33 to 82 years<br>• Height: Between 147 to 185 cm (58 to 73 inches)<br>• Weight: Between 53 to 118 kg (117 to 261 lbs)<br>• Height to Weight Ratio: Between 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb)<br>If patients do not meet these parameters, the EASI derived 12-lead ST | • Assessment of symptoms that may be related to rhythm disturbances of the heart in patients from pediatric to adult age: patients with palpitations.<br>• Assessment of risk in patients with or without symptoms of arrhythmia. Patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patient with left ventricular dysfunction using arrhythmia, e.g.: ventricular ectopy, as method of risk assessment.<br>• Assessment of efficacy of Antiarrhythmia Therapy. Patients with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes, supraventricular arrhythmia or ventricular tachycardia.<br>• Assessment of Pacemaker Function. Evaluation of patients with paroxysmal symptoms, detection of myopotential inhibition, detection of pacemaker mediated tachycardia, evaluation of anti-tachycardia pacing device function, evaluation of rate-responsive physiological pacing function.<br>• Detection of Myocardial ischemia, Patients with chest pain suggestive of Prinzmetal's angina.<br>• Assessment of EASI derived 12-lead ST measurements is recommended |

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| | measurements are not intended for use. EASI derived 12-Lead ECGs and their measurements are approximations to conventional 12-Lead ECGs and should not be used for diagnostic interpretations. | for patients that meet the following parameters.<br>1. Ages: 33 to 82 years<br>2. Heights: 147 to 185 cm (58 to 73 in)<br>3. Weights: 53 to 118 kg (117 to 261 lb)<br>4. Height to Weight ratios: 1.41 to 2.99 cm/kg ( 0.25 to 0.54 in/lb.)<br>• QT measurements can be used by the physician in the risk assessment process indicated for patients with and without symptoms of arrhythmia. QT measurement is intended to be used by competent health professionals in hospital or clinic environment. Composite QT measures the interval only and is not intended to produce any interpretation or diagnosis of those measurements. |
| Target Population | Adult patients | Adult and pediatric patients |
| Intended User | Trained clinicians | Trained clinicians |
| Intended Use Environment | The product is intended for use in hospitals, clinics including physician offices and/or Independent Diagnostic Testing Facility (IDTF) | The product is intended for use in hospitals, clinics including physician offices and/or Independent Diagnostic Testing Facility (IDTF) |

Table 2 provides a high-level summary of the technological characteristics between the subject device and predicate device.

**Table 2: Technological Characteristics Comparison**

| **Similarities** | |
|---|---|
| **Item of Comparison** | **Description/Rationale** |
| Holter Primary Applications, Available Screens, Main Software Views and Holter Scan Modes | Both the subject device, Philips Holter Analysis System, and the predicate device (K010949) provide similar applications, screen views and scan modes.<br><br>Primary applications: Scanner, Central Link, Remote Link and Report Viewer<br>Available screens: Startup screen, Scanning screen, Diagnostic window and Report summary<br>Main Software Views: Scan, Class, Detail, Review, Events, Graph, ST, Strips, Report<br>Scan modes: Page Mode, Superimposition (SI) Mode, Retro Mode, QuickScan Mode |
| Support EASI Hookup type | Both devices support EASI hookup type and provide for EASI-derived 12-lead ECG display and EASI-derived 12-lead ST, 3D. |
| Supported Channel | Both devices support up to 2 to 3 ECG channels. The subject device offers a UI selection for single-channel ECG input. The predicate device can also display and analyze a single channel if only one channel's signal is available. |
| Configure Analysis and Rule setting | Both devices support Atrial, Ventricular, ST , and Morphology analysis and rule setting for each type. The subject device incorporates a minor change to Ventricular Rule Setting by removing the rule setting of 'Minimum Ventricular Run Rate'. |
| Class Edit | Both devices support class edits: Normal, Alternate Normal, Abnormal and Artifact. |
| Arrhythmia and Event Detection | Both devices supported the arrhythmia detection as listed below.<br><br>• PVC (Isolated PVC and Interpolated PVC)<br>• Single Ventricular Ectopic<br>• Ventricular Couplet<br>• Ventricular Triplet<br>• Ventricular Runs<br>• Ventricular Bigeminy<br>• Ventricular Trigeminy<br>• R-on-T<br>• Late Ventricular<br>• Ventricular Tachycardia<br>• Atrial Runs<br>• Atrial Pairs<br>• Atrial Tachycardia<br>• Atrial Bigeminy<br>• Atrial Trigeminy |

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| | • Atrial Fibrillation<br>• Premature Atrial Contraction (PAC)<br>• Late beat<br>• Dropped beat<br>• Bradycardia<br><br>The subject device made enhancement to AFIB detection by replacing the predicate algorithm with the ST/AR AFIB algorithm featuring P wave detection. The feature was cleared in K101521. |
| QT Analysis | Both devices support QT measurement, it reports minimum/average/maximum HR, QT and QTc. |
| ST Analysis | Both devices support ST analysis to report ST Episodes and ST measurements. |
| Pacemaker Analysis | Both devices support Pacemaker analysis. The subject device reports:<br>Sinus Beats, All Paced Beats, Atrial Paced Beats, Ventricular Paced Beats, Dual Paced Beats, Fusion Beats, FTO, FTS, FTC. There is no performance difference between the two devices, only a minor report format update. |
| Caliper | Both devices support the similar Caliper function, which can be used to measure typical distances (e.g., R-R', P-R, QRS, ST, QR, QT). |
| Important Events | Both devices support similar important events with minor change to add the longest R-to-R based on available measurements in the predicate device.<br><br>• Heart Rates: Min/Max Heart Rate, Min/Max Ventricular Run, Min/Max Atrial Run, Max Atrial fibrillation, Max Tachycardia, Min Bradycardia<br>• ST Extrema: Depression, Elevation<br>• Longest Runs: Ventricular, Atrial, Tachycardia, Bradycardia<br>• Other Longest Events: Longest NN, Drop/Late, Longest R – to-R |
| Report Output | Both devices provide similar report output-types. That includes available report sections, content for Analysis Summary, and format of the Analysis Summary. |
| Supported ECG source | Both devices support DigiTrak XT (DTXT) as ECG source inputs. The DTXT has obtained 510(k) clearances (K071733). |
| **Differences** | |
| **Item of Comparison** | **Description/Rationale** |
| Operating system and Hardware Requirement | Philips Holter Analysis System supports Windows 10, Windows 11, Windows Server 2016 and Windows Server 2019 operating systems. The hardware platform requirement has been updated to ensure continued support of the software and strengthen cybersecurity. |

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| Graph (Event Histograms) | Both devices support Graphs: R-R Intervals, N-N Intervals, N-V Intervals<br>V-N Intervals, V-V Intervals, N-N-N percentage and Other Histograms such as 12 lead ST (EASI derived, 3D), QT.<br>The subject device also provides Lorenz plot, which is a scatter plot of each R-R interval based on the preceding R-R interval. |
| Heart Rate Variability | Both devices provide HRV reporting in time domain and frequency domain. Enhancement was made to the HRV analysis reporting by replacing current calculations with advanced data warehouse calculations from PhysioNet and by incorporating Nonlinear HRV to provide more characterization of heart rate variability that linear methods could miss. |
| Interoperability | Holter supports interoperability with Philips IntelliVue Information Center (PIIC) Classic and PIIC iX, IntelliSpace ECG Management System, IntelliBridge Enterprise, and DICOM-based systems. Testing was conducted to demonstrate the connections perform as designed and expected. |

**Substantial Equivalence Summary**

Operational and technological characteristics form the basis for the determination of substantial equivalence of the Philips Holter Analysis System with the legally marketed predicate device 2010 Plus Holter for Windows (K010949). The Philips Holter Analysis System is substantially equivalent to the predicate devices.

## *VII. PERFORMANCE DATA*

**Performance Data Summaries**

The Philips Holter Analysis System has successfully passed all the testing conducted, and the results demonstrated the Philips Holter Analysis System meets the performance claims and supports a determination of substantial equivalence to the predicate device.

**Non-Clinical Tests – Standards**

The performance testing has been conducted for the Philips Holter Analysis System according to IEC 60601-2-47: 2012 and AAMI EC57: 2012 standards. Human Factors and Usability testing has been conducted for the Philips Holter Analysis System according to IEC 62366-1:2015/AMD 1:2020 standard and FDA's Guidance for Industry and FDA Staff Applying Human Factors and Usability Engineering to Medical Devices, dated February 2016. Software validation was conducted according to IEC 62304:2006/ A1:2015 and IEC 82304-1: 2016 standards.

| Standard | FDA Recognition # | Title # |
|---|---|---|
| ISO 14971 Third Edition 2019-12 | 5-125 | Medical devices - Applications of risk management to medical devices |
| IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION | 13-79 | Medical device software – Software Life-cycle Process |
| IEC 82304-1 Edition 1.0 2016-10 | 13-97 | Health software - Part 1: General requirements for product safety |
| IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION | 5-129 | Medical devices - Part 1: Application of usability engineering to medical devices |
| IEC 60601-2-47 Edition 2.0 2012-02 | 3-155 | Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| EC57:2012 | 3-118 | Testing and reporting performance results of cardiac |

| | | |
|---|---|---|
| | | rhythm and ST-segment measurement algorithms |

The following tests are not applicable as the subject device is a software-only device:

- Biocompatibility
- Mechanical Testing
- Electrical Safety and Electromagnetic Compatibility (EMC)

**Non-clinical Bench Tests**

Non-clinical bench testing activities establish the performance and functionality of the subject device. Philips Holter Analysis System was evaluated against all applicable standards and internal procedures and successfully passed all verifications and validations. The results demonstrated that Philips Holter Analysis System meets all claims and supports a determination of substantial equivalence to the predicate. Testing has demonstrated that the Philips Holter Analysis System is safe and effective as compared to the predicate for its intended use, intended users, and use environment.

*No new issues of safety or effectiveness are introduced as a result of using this device.*

**Clinical Studies**

The Philips Holter Analysis System, like the predicate device, does not require clinical trials.

FDA recognized standards, software verification and validation, usability validation, and risk management activities have taken place for the Philips Holter Analysis System.

Based upon the design, indications for use, classification, usability and performance testing, the Philips Holter Analysis System is substantially equivalent to the listed predicate device.

*No new issues of safety or effectiveness are introduced as a result of using this device.*

## *VIII. CONCLUSIONS*

The results of the substantial equivalence assessment, taken together with performance testing, software verification and validation, human factors and usability validation demonstrate that the Philips Holter Analysis System does not raise different questions of safety and effectiveness when compared to the predicate device (K010949). The subject device performs as intended and has performance characteristics that are substantially equivalent to the predicate device (K010949).