DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2017

Cardiac Insight, Inc.
Dan Tylutki
VP of QA & RA
3230 Carillon Point
Kirkland, Washington 98033

Re: K162503
Trade/Device Name: Stealth System S300
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK
Dated: February 20, 2017
Received: February 21, 2017

Dear Dan Tylutki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162503

Device Name
Stealth System S300

Indications for Use *(Describe)*
The Stealth System S300 is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath or who are at risk of developing atrial fibrillation and where a software-assisted analysis of an ambulatory ECG could identify potential cardiac causes of these symptoms. It includes a prescription only, single use, continuous ECG recorder that can be worn up to 7 days during activities of daily living.

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) PREMARKET NOTIFICATION

EXECUTIVE SUMMARY (9/26/2016 Update)

1. SUBMITTER'S INFORMATION

Company Name: Cardiac Insight, Inc.
Company Address: 3230 Carillon Point
Kirkland, WA 98033
Company Phone: 206-596-2060
Contact: Dan Tylutki / dtylutki@cardiacinsightinc.com

Trade Name: Stealth System S300™
Common Name: Medical magnetic tape recorder
Classification Name(s): Recorder, Magnetic Tape, Medical
Computer, Diagnostic, Programmable
Product Code(s): DSH, DQK
Regulatory Class: II
CFR Section(s): 21 CFR 870.2800, 21 CFR 870.1425

2. PREDICATE DEVICE IDENTIFICATION

Device Name	Clearance Number	Regulation # / Product Code
ZIO SkyRunner (SR)	K143513	870.2800 / DSH
Electrocardiogram (ECG)		870.1425 / DQK
Monitoring Service		870.2920 / DXH

The predicate is a Class II device.

3. INTRODUCTION

The Stealth System S300 is an electrocardiogram (ECG) recording and analysis system designed to record and analyze single lead ECG data. It employs a patient-worn recording device to collect ambulatory ECG data. The data is then transferred, stored, analyzed, and sorted to generate a report of findings from the analysis of data. A clinician uses the report to aid the diagnosis of cardiac arrhythmias in adult patients.

The Stealth System S300 is substantially equivalent to the ZIO SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service as the intended use is the same and the performance is comparable.

Stealth System S300 ECG recorder and ECG analysis performance was quantified for the claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels that satisfy requirements and minimize safety or efficacy concerns.

4. BACKGROUND

The Stealth System S300 enables continuous ambulatory ECG data collection for up to 7 days and provides the clinician an ECG analysis report within minutes of ECG data transfer from the recorder. The 7-day duration increases the likelihood any transient

arrhythmias a patient may be experiencing will be captured over those found with commonly used 24-hour and 48-hour Holter recorders.

Recording and analysis systems currently on the market can process recordings of this length but the elapsed time between recording and an analysis report available for clinical review is days, if not weeks. Such systems often involve a third party, resulting in higher costs and a less than optimal patient and provider experience.

The Stealth System S300 enables Cardiac Insight to provide a complete ambulatory ECG recorder and analysis system with clinically significant diagnostic capability at a lower cost and with a simplified provider and patient experience.

5. INTENDED USE & INDICATIONS FOR USE

The Stealth System S300 is intended for continuous single lead ECG recording and presentation of ECG trace data and associated analysis information to assist clinicians with the diagnosis of cardiac arrhythmias. The Sensor is not intended for use should defibrillation be required; the Sensor should be removed before defibrillation.

The Stealth System S300 is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, dizziness, anxiety, fatigue, syncope, pre-syncope, light-headedness, shortness of breath or who are at risk of developing atrial fibrillation and where a software-assisted analysis of an ambulatory ECG could identify potential causes of these symptoms. It includes a prescription only, single use, continuous recording ECG recorder that can be worn up to 7 days during the activities of daily living.

Clinician’s Responsibility:

Not all cardiac conditions can be detected by an ECG analysis and many potentially detectable conditions are not always present, or may be transitory and not present in a specific ECG recording. The symptoms, physical exam, patient / family history and additional information are critical for a clinician’s overall assessment of a patient's cardiac health.

It is the clinician’s responsibility to ensure proper ECG data collection, review and interpretation and ultimately make a diagnosis of the individual’s cardiac health and/or risk of cardiac events. Proper decisions of when more testing is indicated or referral for specialty care is dependent upon good clinical judgment.

6. DEVICE DESCRIPTION

The Stealth System S300 consists of three components: (1) Sensor, (2) Smart Cable, and (3) StealthView personal computer software (PC Software). No component of the system is provided sterile. The Stealth System S300 is depicted in Figure 10-1 (below).

The Sensor is a 7-day, wearable, single use, disposable recorder that detects and records ECG signals and records patient event markers. It is intended for ambulatory, adult patients. Recorded data is retrieved by connecting the Sensor to StealthView software using the Smart Cable after the Sensor has been removed from the patient. StealthView software analyzes the recorded ECG signal and provides a report of heart rhythms for clinician review.

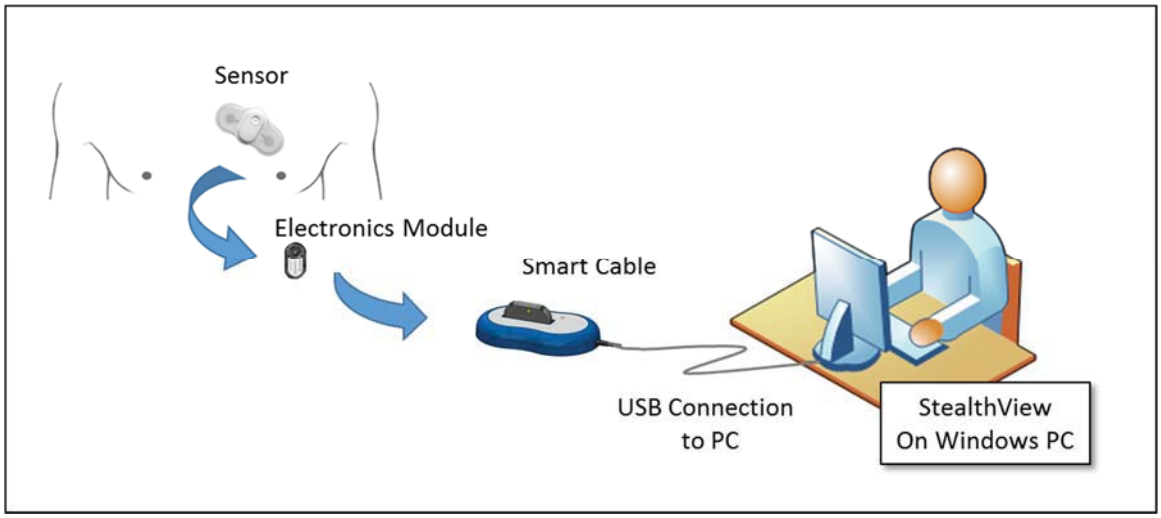

Figure 10-1: Stealth System S300

Sensor

The Sensor is a flexible circuit with biocompatible skin adhesive and two electrodes (electrode assembly) on one side and an electronics module on the other side. The electrode assembly integrates two hydrogel-coated electrodes providing single channel modified Lead II ECG recording capability. The electronics module connects to the electrode assembly by means of conductive adhesive and can be detached from the electrode assembly at the end of ECG recording. The electronics module contains a push-button switch, a microcontroller, an ECG front end, non-volatile storage, and associated circuitry required to support ECG recording and storage. A single, coin-cell battery supplies power to the electronics module. The push-button switch both activates the Sensor and allows patient event markers during recording. The non-volatile memory stores the ECG signal recorded from the patient.

The Sensor contains embedded software (firmware) to control the operation of the device based on external inputs. The firmware is loaded onto the microcontroller's internal memory during the manufacturing process and cannot be modified after Sensor assembly. Once ECG recording begins, the Sensor continues to record ECG data until the non-volatile storage is full at which point recording is terminated. A removable foam cover protects the electronics module during patient use and allows easy access to the recorded ECG after patient use.

Smart Cable

The Smart Cable connects between the Sensor and StealthView (host computer) and receives power from the host computer's USB port. The Smart Cable contains integrated electronics and embedded software (firmware) which enables the high-speed transfer of recorded ECG data. Smart Cable firmware cannot be changed after manufacture and is not user accessible.

StealthView Software (& host computer)

StealthView software is installed on a host computer – a customer-supplier personal computer loaded with the Microsoft Windows® operating system and compliant to

Cardiac Insight's minimum specifications.

StealthView initiates transfer of the recorded ECG when a Sensor's electronics module is connected to the host computer. While the clinician enters relevant patient demographic information, StealthView performs ECG analysis. After a few minutes a report is created containing patient demographics, detected arrhythmias, heart beat statistics, and ECG 'snapshots' based on the analysis performed by StealthView's algorithms. Snapshots are carefully structured selections from the ECG recording of varying lengths designed to illustrate the reported condition. The StealthView analysis includes detection and reporting of the following arrhythmias: atrial fibrillation, supraventricular tachycardia, pre-mature ventricular contractions (PVCs), tachycardia and bradycardia events, and pauses. The report is presented as a PDF file. The report may be edited so a clinician may document their review and notations regarding the analysis provided.

There are no accessories associated with the Stealth System S300.

7. SUBSTANTIAL EQUIVALENCE

The technological principle for both the subject and predicate devices is recording and analysis of the lateral view of the electric activity in the cardiac muscle i.e., a modified Lead II vector. The recorded ECG signal is processed using multi-band frequency filters for noise reduction and increased precision of the beat detection and classification. The ECG analysis software (StealthView) uses temporal and amplitude beat measurements along with beat-to-beat correlation to identify beat types and the heart rate (R-R interval) irregularities for arrhythmia detection.

ECG Recorder Comparison:

The subject and predicate device are based on the same technological elements.

Table 10-1: ECG Recorder Comparison: Sensor vs. ZIO SR Patch Recorder

Technological Element	Subject Device (Sensor)	Predicate Device (ZIO SR Patch Recorder)
Lead Vector	Modified Lead II	Modified Lead II
# of Channels	1	1
Application / Wear	Hydrocolloid adhesive, body worn	Hydrocolloid adhesive, body worn
Electrodes	• 2 electrodes • Non-detachable, integrated with recording electronics • Conventional silver – silver chloride with hydrogel	• 2 electrodes • Non-detachable, integrated with recording electronics • Conventional silver – silver chloride with hydrogel
Use Environment	Ambulatory outpatient	Ambulatory outpatient
Recording Type	Continuous	Continuous
Recording Duration	Up to 7 day	Up to 14 day
Adult / Pediatric	Adult	Adult
Power Source	Non-rechargeable battery	Non-rechargeable battery
Single Use / Reusable	Single use, disposable	Single use, disposable

ECG Data Transfer Comparison:

Table 10-2: ECG Data Transfer Comparison: Smart Cable vs. ZIO SR Wireless Gateway

Technological Element	Subject Device (Smart Cable)	Predicate Device (ZIO SR Wireless Gateway)
Data Transfer Interface	Wired USB	Bluetooth Technology, Cellular Phone Technology
Single Use / Reusable	Reusable	Reusable

The technological elements used to transfer recorded ECG data to the ECG analysis component of the system differ between the subject and predicate device. The predicate device uses wireless technology while the subject device uses a physical cable connection. A wired connection for data transfer interface is more reliable and secure and raises no new issues with regard to safety and efficacy for the subject device and in all practicality, reduces the concern. Therefore, the difference in data transfer interface has no material effect on a substantial equivalence determination of the subject device as compared to the predicate device.

ECG Analysis Comparison:

The subject and predicate device are based on the same technological elements.

Table 10-3: ECG Analysis Comparison: StealthView vs. ZIO ECG Utilization Service System

Technological Element	Subject Device (StealthView)	Predicate Device (ZIO ECG Utilization Service System)
Architecture	ECG analysis is performed on pre-recorded data using computer assist	ECG analysis is performed on pre-recorded data using computer assist
ECG Vector Analyzed	Modified Lead II	Modified Lead II
Analysis Method	Beat-by-beat QRS detection with rhythm analysis algorithms	Beat-by-beat QRS detection with rhythm analysis algorithms

Technological Element	Subject Device (StealthView)	Predicate Device (ZIO ECG Utilization Service System)
Rhythms Detected	• atrial fibrillation (AF) • supraventricular tachycardia (SVT) • ventricular tachycardia (VT) • premature ventricular contractions (PVCs) • tachycardia and bradycardia events • pauses • Heart rate stats: normal, fastest, slowest, average	• atrial fibrillation (AF) • supraventricular tachycardia (SVT) • ventricular tachycardia (VT) • premature ventricular contractions (PVCs) • tachycardia and bradycardia events • pauses • Heart rate stats: normal, fastest, slowest, average • AV block • Ventricular Trigeminy • Ventricular Bigeminy • VF / TdP / PVT (CU)
Analysis Output	Report with arrhythmias, heart rate statistics, ECG snapshots	Report with arrhythmias, heart rate statistics, ECG snapshots
Report Generation Time	Minutes	Days
Diagnosis	None. No diagnostic interpretation is provided but rather an analysis for review by the clinician to render a diagnosis based on clinical judgement and experience.	None. No diagnostic interpretation is provided but rather an analysis for review by the clinician to render a diagnosis based on clinical judgement and experience.
Interactive ECG Review	Software tools for interactive review of the ECG data and results.	Software tools for interactive review of the ECG data and results.

Table 10-3 continued

None of the differences outlined in the tables above raise new questions of safety or effectiveness. Therefore, Cardiac Insight believes the subject device to be substantially equivalent to the predicate device.

Note: Section 12 (Substantial Equivalence Discussion) of this submission contains a detailed analysis.

8. COMPLIANCE TESTING

Biocompatibility

The biocompatibility evaluation of the Stealth System S300 was conducted in accordance with the FDA Guidance "*Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process*,'" June 16, 2016, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and testing within a risk management process*," as recognized by FDA.

The Sensor is categorized according to ISO 10993-1 as a surface-contacting device (skin) for prolonged exposure (exceeding 24 hours but not 30 days). Sensor testing included ISO-10993-1 tests applicable to a skin surface-contacting ECG electrode component:

- Cytotoxicity
- Skin Irritation
- Skin Sensitization

Biocompatibility is not a user risk for the Smart Cable and StealthView software components of the Stealth System S300 and therefore was not evaluated.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Sensor and Smart Cable components of the Stealth System S300. The system complies with the IEC 60601-1 and IEC 60601-2-47 standards for safety and the IEC 60601-1-2 standard for EMC.

The following standards were considered because of the selected Product Codes, but were deemed not relevant.

3-106 AAMI/ANSI IEC 60601-2-25 (Medical electrical equipment — Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs) does not apply because this standard is for multi-lead, multi-vector electrocardiographic monitoring equipment with detachable leads. The Stealth System is an integrated lead, single vector, post-ECG recording analysis device exhibiting none of the product safety concerns of devices for which IEC 60601-2-25 applies. Therefore, compliance with this Standard does not apply to the Stealth System.

3-129 AAMI/ANSI EC53:2013 (ECG Trunk Cables and Patient Leadwires (Cardiovascular)) does not apply because this standard is for interchangeability of devices with detachable leads. The Stealth Systems Sensor leads are fully integrated with the electronics and inaccessible to the user; interchangeability of leads between ECG monitors does not apply to the Sensor. Therefore, compliance with this Standard does not apply to the Stealth System.

Software Verification and Validation

Software verification and validation tests were conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" and "*Compliance on Off-The-Shelf Software Use in Medical Devices*". The software for this device is considered a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor / non-serious injury to the patient through incorrect or delayed information.

Animal and Clinical Studies

Animal and clinical studies were not conducted for the Stealth System S300 submission. Bench testing alone is sufficient and was completed in accordance with applicable FDA recognized consensus standards for ambulatory ECG recorder and analysis systems.

Compliance Testing Summary

Based on the bench performance test results documented in the test reports, the Stealth System S300 was found to have a safety and effectiveness profile similar to that of the predicate device.

9. CONTRAINDICATIONS / PRECAUTIONS

The Stealth System S300 is contraindicated for patients with known allergies or hypersensitivities to medical grade hydrocolloid adhesives or hydrogel.

The Stealth System S300 is contraindicated for patients with potentially life-threatening arrhythmias, or who require inpatient monitoring or immediate analysis of their ECG.

The Stealth System S300 is contraindicated for patients with an implantable pacemaker in use. Paced beats interfere with the analysis of the ECG and may cause misclassification of beats and rhythms.

The Stealth System is not intended for pediatric patients.

These contraindications and precautions are essentially the same as those of the predicate device.

10. CONCLUSION

Based on thorough verification and validation testing and the substantial equivalence comparison with the predicate device, Cardiac Insight concludes the Stealth System S300 is substantially equivalent to the legally marketed predicate, ZIO SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service.