December 29, 2020

Global Instrumentation LLC
% Rafael Aguila
Responsible Third Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K202456
Trade/Device Name: M5 Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH, DXH
Dated: December 23, 2020
Received: December 23, 2020

Dear Rafael Aguila:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202456

Device Name

M5 Recorder

Indications for Use *(Describe)*

The M5 Recorder is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The M5 Recorder is intended for use by adults and all pediatric subgroups (weighing 10 kg or more).

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.

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I. Submitter

Submitted by: Global Instrumentation LLC.
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Date Prepared: December 17th, 2020

II. Device

510(k) Number:	K202456
Trade Name:	M5 Recorder
Model Number:	M5
Regulation Number:	21 CFR 870.2800
Review Panel:	Cardiovascular
Regulation Name:	Medical Magnetic Tape Recorder
Regulatory Class:	II (Two)
Product Code:	DSH, DXH
Manufacturer:	Global Instrumentation, LLC 8104 Cazenovia Rd. Manlius, NY 13104

III. Predicate Device

510(k) Number:	K163535
Trade Name:	myPatch®sl
Model Number:	3000sl
Regulation Number:	21 CFR 870.2800
Review Panel:	Cardiovascular
Regulation Name:	Medical Magnetic Tape Recorder
Regulatory Class:	II (Two)
Product Code:	DSH
Manufacturer:	dms-service, llc 11845 W. Olympic Blvd, Ste 880W Los Angeles, CA 90064

NOTE: This predicate has not been subject to a design-related recall.

IV. Secondary Predicate Device

510(k) Number:	K143513
Trade Name:	Zio Skyrunner (SR) Electrocardiogram (ECG) Monitoring Service (Zio SR Patch Recorder with Bluetooth Technology)
Model Number:	Zio SR
Regulation Number:	21 CFR 870.2800
Review Panel:	Cardiovascular
Regulation Name:	Medical Magnetic Tape Recorder
Regulatory Class:	II (Two)
Product Code:	DSH, DQK, DXH
Manufacturer:	iRhythm Technologies, Inc. 650 Townsend Street, Ste 380 San Francisco, CA 94103

V. Description of the Device

The M5 Recorder is a small, lightweight ambulatory electrocardiograph (ECG) recorder that records ECG continuously. The M5 records 1 or 3 channels of ECG up to 21 days. The battery duration of the M5 is dependent on the configured settings of sample rate and channel selection. The device is composed of the ECG recorder that can be utilized with a patch electrode or with a patient cable lead set using off the shelf electrodes intended for long-term monitoring. The device snaps onto the patch electrode or patient cable lead set and automatically begins recording. The recording will continue until either the M5 completes the programmed monitoring session, is removed from the Patch Electrode or patient cable, or the battery is depleted.

At the end of the recording, the device can be plugged into a PC via the M5 USB cable. The ECG recording can be transferred to a PC where processing software can transfer the data to a format that can be processed through recording processing software provided by recording processing software manufacturers and analyzed by qualified healthcare providers. The M5 recorder acquires ECG data and does not perform any data processing or arrhythmia analysis of the ECG data. Only the M5 Recorder is part of this 510K application.

During the recording period the patient wears the M5 Recorder with the patch electrode on the upper chest near the sternum. If using the M5 Recorder with the patient cable, the patient will wear off the shelf electrodes (2 – 5) positioned on the torso. The M5 Recorder can be worn continuously up to 14 days with the same patch electrode and up to 4 days with the patient cable and same set of off the shelf electrodes.

The M5 Recorder consists of a microprocessor, measuring circuit, memory, data storage, light emitting diode (LED), and contacts to the electrode. In addition to that, the M5 Recorder contains firmware to control the collection of the ECG data and allows transfer to the processing software. The M5 Recorder has an internal Bluetooth radio that may be utilized with a host ambulatory ECG analysis system (such as the Global Instrumentation M12A application) to allow the qualified health care provider a view of the patient's ECG immediately following hook-up. The LED on the M5 Recorder will flash. This provides visual confirmation to the professional that the recorder is actively collecting data.

The M5 recorder also has a button on the recorder. The primary function of the button is to

provide an event feature where the patient presses the button on the recorder when they feel a symptom. The LED will flash to provide feedback to the patient that the event marking has occurred. The button also allows for a battery status check.

The associated spare parts that are part of the M5 Recorder system are the M5 Patch Electrode, M5 Patient Cable, M5 USB Cable, and GI Wall Charger.

Components, Spare parts and Collateral Devices – Overview

M5 Recorder

The M5 Recorder has interfaces to a compatible M5 Patch Electrode, M5 Patient Cable, and M5 USB Cable. The Recorder is reusable and rechargeable. The battery is a rechargeable lithium polymer battery with built-in protection circuit. Charging the M5 Recorder battery is done by use of the M5 USB cable with a proprietary connector which can only be connected to the M5 Recorder when it is not connected to the M5 Patch Electrode or M5 Patient Cable. The Recorder contains internal non-volatile storage that stores ECG data until uploaded to host system. The M5 Recorder also contains firmware for recording ECG, storing ECG, and user interface. When the recorder is connected to the host system through the M5 USB Cable, the recorded ECG files are accessible via a proprietary communication protocol. All M5 Recorder data files are in a proprietary file format. All communication to the M5 Recorder requires proprietary encrypted authentication.

The recorder has a serial number and product number in a GS-128 bar code format to secure the traceability of the equipment and the data during and after recordings.

The case of the M5 Recorder is a Valox 357U polycarbonate (PBT) for medical device applications and has ISO 10993 certification.

M5 Patch Electrode

The electrode is non-sterile and disposed of after a single use. The patch electrode (spare part to M5 Recorder) is a passive part. The electrode consists of one layer of one-sided adhesive tape that runs the full length of the electrode. This adhesive tape allows the electrode to be placed on the upper sternum. The electrode gel is located on the underneath side of the adhesive tape. Through this electrode gel the ECG of the patient is recorded. The M5 Patch Electrode provides a single channel ECG recording. The top side of the electrode has a plastic cradle that holds the M5 Recorder in place and provides an electrical connection to the patch electrode conductor path. The conductor paths are flex strips that run between the cradle and the electrode gel. A release liner is placed on the underside of the electrode. The release liner covers the adhesive tape and the electrode gel. This liner is peeled off when placing the M5 Patch Electrode on the upper sternum. The electrode must be connected to the M5 Recorder to have any practical use.

Per the U.S. FDA Class II Special Controls Guidance Document: Electrocardiograph Electrodes, issued on July 21, 2011 “the FDA has determined that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance to address the issues identified in this guidance.” The scope of the guidance includes “bare ECG electrodes or ECG electrodes that incorporate as part of their design, a conductive gel, an adhesive system or a lead wire”. Per this guidance, we have the device specifications, composition, formulation, component specifications, engineering drawings with dimensions & composition, written description, description of how the M5 Patch Electrode connects to the M5 Recorder and a list of features and specifications in tabular format.

M5 Patient Cable (lead set)

The M5 Patient Cable (spare part to M5 Recorder) is a reusable lead set option for collecting ECG recordings in single or three channel modes. The patient cable is available in 2 lead, 3 lead, 4 lead and 5 lead options and uses off the shelf electrodes suited for ambulatory ECG

monitoring. The patient cable features a custom connector that attaches to the M5 Recorder. The placement of the electrodes are left arm (LA), right arm (RA), left leg (LL), right leg (RL), and V. The V lead electrode may be positioned in any of the precordial (V1 – V6) placements based on physician preference.

The M5 Patient Cable is used with standard electrodes intended for longer duration ambulatory ECG recording. The off the shelf electrodes feature a snap which provides connection to the leads of the M5 Patient Cable.

M5 USB Cable

The M5 USB Cable (spare part to M5 Recorder) is used to recharge the M5 Recorder and to upload the stored ECG data from the recorder to a host system. The M5 USB Cable features a proprietary connector design to match to the M5 Recorder. The opposite end of the cable uses a standard USB Type A male connector.

GI Wall Charger

GI Wall Charger is a 60601-1 compliant medical grade power supply with integral USB jack used with the M5 USB Cable for charging the M5 Recorder.

VI. Indications For Use

M5 Recorder – Indications for Use

The M5 Recorder is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The M5 Recorder is intended for use by adults and all pediatric subgroups (weighing more than 10 Kg).

M5 Recorder – Intended Use

The M5 Recorder is a small digital ambulatory ECG recorder intended for use by professionals to acquire ECG data from a patient in a clinical, point of care or at a patient setting.

The M5 Recorder uses a rechargeable lithium polymer battery and can record ECG up to 21 days (3 channels) on the torso of a patient through a M5 Patch ECG electrode or M5 lead set and standard electrodes (length or recording time is based on the sample rate and channel selection). The patient's ECG is recorded to the M5 Recorder and then transferred via the M5 USB cable to a PC-based ambulatory ECG analysis system (such as the Global Instrumentation M12A application) for review by physicians or other qualified personnel.

Due to the continual wearing of an ambulatory ECG monitor, this is a medical device that is used both in professional healthcare facilities and outside those facilities. This description meets the definition of a home use device. The M5 Recorder is intended for use by adults and pediatric sub-groups (weighing more than 10 Kg). The intended use, expected service life and conditions for transport and storage were taken into consideration for selection and treatment of materials used in the construction of the M5 Recorder.

VII. Comparison of Technological & Performance Characteristics with the Predicate Devices

The M5 Recorder is substantially equivalent in hardware, software and performance to the primary predicate DMS-Service myPatchsl (K163535) and the Faros Mobile (K182030) Secondary Predicate. Table 1 shows a comparative analysis of characteristics between the predicate and subject devices.

Table 1: Technological Comparison of M5 Recorder with Predicate Device

Technical Equivalence	M5 Recorder Subject Device	myPatchsl Primary Predicate Device	Zio SR Patch Recorder Secondary Predicate Device	Similarities/Differences
Type of ECG Recorder	Patch & attachable external lead option	Patch & attachable external lead option	Patch	(Primary) Similar. The predicate device provides an attachable external lead option for 3 channel recordings. The M5 provides attachable external lead options for 2 and 3 channel recordings. There is no change to the safety and effectiveness of the device. (Secondary) Similar. Supports patch, but no external lead option.
Indications for Use	The M5 Recorder is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The M5 Recorder is intended for use by adults and all pediatric subgroups (weighing more than 10 Kg).	myPatchsl is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The myPatchsl is intended for use by adult and pediatric subgroups.	The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate	(Primary) Similar. The M5 Recorder indications for use includes a weight minimum for the pediatric subgroup. (Secondary) Similar. Symptom indications for use are the same. The secondary predicate includes an analysis and reporting service in addition to the Zio Patch Recorder.

			measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.	
Target Population	Adult and pediatric subgroups (weighing more than 10 Kg)	Adult and pediatric subgroups	Adult patients 18 years or older	(Primary) Similar. The primary predicate does not set a minimum weight level (Secondary). Different. The secondary predicate restricts use to 18 years or older.
Environment of Use	Clinical site/facility, point of care or at a patient setting.	Clinical site/facility, patient point of care or at a patient setting.	Clinical site/facility, point of care or at a patient setting.	(Primary & Secondary) Same
Number of ECG Channels	1, 2, 3	1, 2 or 3	1	(Primary) Same (Secondary) Similar. Provides a single channel recording only.
Arrhythmia Detection	None	None	None	(Primary & Secondary) Same. neither device provides arrhythmia detection functionality on the recorder.
Alarm Systems	None	None	None	(Primary & Secondary) Same. Neither device provides alarm functionality and the 60601-1-8 is not applicable.
Patient Event Marking	Yes, by button press	Yes, by taping twice on the recorder housing	Yes, by button press	(Primary) Similar. There is no change to the safety and effectiveness of the device.

				(Secondary) Same
Continuous Wear Time	Up to 14 Days	Up to 14 Days	Up to 14 Days	(Primary & Secondary) Same. The battery in the M5 Recorder has been tested and runs up to 19.9 days. If we rate it down 20% (standard battery wear and tear), we can expect to get a minimum of 14 days of recording throughout the life of the M5 Recorder. We are comfortable in quoting a 14 day recording period.
Recording Format	Continuous	Continuous	Continuous	(Primary & Secondary) Same
Power Requirement	Rechargeable Lithium Polymer battery; 3.7v 500 mAh with USB charging	Rechargeable Lithium Polymer battery; 3.7v 600 mAh with USB charging	2 Lithium Manganese Dioxide Coin Cells; single-use	(Primary) Similar. The battery is still a rechargeable 3.7v Lithium Polymer. There is no change to the safety and effectiveness of the device. (Secondary) Different. The secondary predicate uses a non-rechargeable, single-use battery. There is no change to the safety and effectiveness of the device.
Battery Life (on single charge)	Up to 14 Days	Up to 14 Days	Up to 14 Days	(Primary & Secondary) Same. The battery in the M5 Recorder has been tested and runs up to 19.9 days. If we rate it down 20% (standard battery wear and tear), we can expect to get a minimum of 14 days of recording throughout the life of the M5 Recorder. Thus we are

				comfortable in quoting a 14 day recording period.
Storage Medium	8GB internal storage	8GB internal storage	Internal Storage	(Primary & Secondary) Same
External Data Interface	USB cable Bluetooth	USB cable	USB cable Bluetooth	(Primary) Similar (Secondary) Same
Recorder Dimensions	14 x 32 x 54 mm	10 x 40 x 49 mm	12.7 x 37 x 51 mm	(Primary) Similar. There is no change to the safety and effectiveness of the device. (Secondary) Similar
Recorder Weight	26 grams	25 grams	25 grams	(Primary & Secondary) Same
Calibration	Calibration not required	Calibration not required	Calibration not required	(Primary & Secondary) Same
Frequency Response	0.05 Hz – 60Hz @ 200sps 0.05 Hz – 100Hz @ 250sps 0.05 Hz – 175 Hz @ 500sps	0.05 -20 Hz @ 128 sps 0.05 - 40Hz @ 256 sps 0.05-55 Hz @ 512 sps 0.05Hz-175Hz @ 1024 sps	0.5 to 30Hz @ 200 sps	(Primary) Similar. There is no change to the safety and effectiveness of the device. The IEC 60601-2-47 standard requires a minimum frequency response of .05-40Hz. Any upper frequency response of 40Hz, or higher, meets the frequency response performance required by all applicable standards, including IEC 60601-2-47 “Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems”. The devices provide equivalent performance as they both provide upper frequency response limits >= 40 Hz. So

				performance is equivalent as all devices have been tested meet IEC 60601-2-47 required performance requirements. (Secondary) Similar
Input Impedance	>10 Ohms	>10 Ohms	>10 Ohms	(Primary & Secondary) Same
Resolution	16 bits	12 bits	10 bits	(Primary & Secondary) Similar. There is no change to the safety and effectiveness of the device. Performance is equivalent to IEC 60601-2-47 for all devices.
Performance Standard	Design Verification IEC 60601-2-47	Design Verification IEC 60601-2-47	Design Verification IEC 60601-2-47	(Primary & Secondary) Same
Safety				
ISO, IEC, or ANSI/AAMI Standards Met	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47 IEC 60601-1-11	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47 IEC 60601-1-11	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47 IEC 60601-1-11	(Primary & Secondary) Same
Biological Equivalence				
Medicinal Substances	N/A	N/A	N/A	(Primary & Secondary) Same.
Tissue	N/A	N/A	N/A	(Primary & Secondary) Same.
Blood Products	N/A	N/A	N/A	(Primary & Secondary) Same.
Body Fluids Contacted by Device	N/A	N/A	N/A	(Primary & Secondary) Same.

Type of Contact to Skin	Non-invasive	Non-invasive	Non-invasive	(Primary & Secondary) Same.
Mucosal Membrane Contact	N/A	N/A	N/A	(Primary & Secondary) Same.
Duration of Skin Contact	Up to 14 Days	Up to 14 Days	Up to 14 Days	(Primary & Secondary) Same.
Sterile vs Non-Sterile	N/A	N/A	N/A	(Primary & Secondary) Same All devices are non-sterile.
Biological Compatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1	(Primary & Secondary) Same
Clinical Equivalence				
Medical Purpose	Ambulatory ECG	Ambulatory ECG	Ambulatory ECG	(Primary & Secondary) Same
Single Use Patch Electrode	Single Use Patch Electrode (single channel)	Single Use Patch Electrode (2 channel)	Recorder, Single Use Patch Electrode (single channel)	(Primary) Similar The myPatchsl has 3 electrodes integrated in the patch to provide a 2 channel recording. The M5 has 2 electrodes integrated in the patch to provide a single channel recording. There are no technological characteristics that would raise different questions of safety and effectiveness. (Secondary) Similar. The secondary predicate device utilizes single use batteries.
Single Use Standard Electrode	Attachable external lead option used with single use standard electrode	Attachable external lead option used with single use standard electrode	No attachable lead option	(Primary) Same (Secondary) Different. No additional lead option for use with standard electrode.

Recording Standard	Holter	Holter	Holter	(Primary & Secondary) Same Standard is IEC 60601-2-47
Patch Electrode Placement **(Anatomical Site)**	Left Sternum or Center Vertical Sternum	Left Sternum or Center Vertical Sternum	Left Sternum	(Primary) Same. (Secondary) Similar. The secondary predicate only indicates left sternum placement.
Lead Set Electrode Placement	Additional attachable external lead option for 3 channel recording.	Additional attachable external lead option for 3 channel recording.	No additional lead option offered.	(Primary) Same. (Secondary) Different. Additional lead option not offered.
Recording Period	Up to 21 Days	Up to 14 Days	Up to 14 Days	(Primary & Secondary) Different: more and more practitioners and researchers are requesting longer recording times from ambulatory ECG recorders with clinical data confirming the increased value of longer-term recordings in detecting cardiac arrythmias. This is an improvement to the device. There are no technological characteristics that would raise different questions of safety and effectiveness. (Note: Electrode replacement and recharging of the recorder battery may be needed to achieve the full duration of recording)

VIII. Performance Data

The M5 Recorder was designed and tested for compliance with the applicable clauses of the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 - Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 - Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.1 2010-01 - Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-11 Edition 2.0 2015-01 - Medical electrical equipment – part 1-6: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC/EN 60601-2-47 Edition 2.0 2012-02 - Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 62304:2006/A1:2016 - Medical device software - Software life cycle processes
- IEC/EN 62366-1 Edition 1.0 2015-02 - Medical devices - Application of usability engineering to medical devices
- ISO 14971:2007-03-01 - Medical devices - Application of risk management to medical devices
- ANSI AAMI EC53:2013 - ECG trunk cables and patient leadwires
- ANSI/AAMI EC12:2000/(R) 2015 - Disposable ECG Electrodes
- U.S. FDA - Class II Special Controls Guidance Document: Electrocardiograph Electrodes (July, 2011)

Biocompatibility Testing:

The biocompatibility evaluation was conducted in compliance to the FDA GLP Regulations, 21 CFR Part 58 and ISO 10993: Biological Evaluation of Medical Devices, Part 5: Tests for in vitro cytotoxicity, Part 10: Tests for irritation and skin sensitization, and Part 12: sample preparation and reference materials.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Mechanical Testing

The following tests were successfully performed in accordance with IEC 60601-1:

- Power input
- Humidity preconditioning treatment
- Accessible parts,
- Legibility of markings
- Durability of marking
- Leakage current test

- Dielectric voltage withstand
- Ball pressure
- Defibrillation-proof applied parts-Measurement of hazardous electrical energies
- Defibrillation-Proof Applied Parts or Patient connection of Defibrillation
- Temperature test
- Ingress protection
- Cleaning
- Measurement of power
- Single fault conditions
- Push test
- Impact test
- Drop test
- Mold stress
- Simulated use testing

Usability Testing

The clinical usability testing was implemented and overseen by Global Instrumentation LLC personnel with volunteer subjects acting as surrogate patients during the testing. The usability studies started May 7, 2019 and continued through March 10, 2020. The Human Factors and Usability Engineering to Medical Devices guidance has been followed in tandem with IEC 62366-1:2016" Application of usability to medical devices" and IEC 60601-1-6 Edition 3.1 2015 "General requirements for basic safety and essential performance – Collateral standard: Usability".

There were a total of 64 subjects that wore the M5 Recorder and components during daily activities. Total days of wear involving the M5 Recorder and components was 455 days.

Clinical users participated in the U5 Usability Test. The clinical user group comprised a cross section of experience in using ambulatory ECG recorders and clinical positions representative of the intended M5 Recorder user base.

Testing consisted of 5 independent usability tests: U1, U2, U3, U4 and U5. The U5 study included clinical users working with the M5 System and volunteer subjects. The usability testing involved all aspects of the M5 System including the M5 Recorder, M5 Patch Electrode, and M5 Patient Cable.

The testing was successful in validating the clinical and patient usability of the M5 System based on the usability goals and pass/fail criteria established in each study.

Clinical Studies:

No clinical studies were performed as appropriate verification and validation for the subject device were achieved in accordance with the acceptance criteria for the predicate devices and from the results of the bench and usability testing.

Animal Study:

No animal studies were performed as appropriate verification and validation for the subject device were achieved in accordance with the acceptance criteria for the predicate devices and from the results of the bench and usability testing.

Risk Management

The Risk Management process was performed according to ISO 14971, 2nd ed.

IX. Conclusions

Based on the information presented in this 510(k) premarket notification, the M5 Recorder is considered substantially equivalent to the currently marketed predicate devices.