



July 15, 2016

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

DMS-Service LLC
Lynda Cole
Owner/manager
11845 W. Olympic Blvd Ste 880w
Los Angeles, California 90064

Re: K160704
Trade/Device Name: myPatch-s
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: May 12, 2016
Received: May 18, 2016

Dear Lynda Cole:

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 yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160704

Device Name

myPatch®s

Indications for Use (Describe)

myPatch®s 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 myPatch®s is intended for use by Adults and all Pediatric subgroups.

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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510(k) Summary K160704/S002



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February 26, 2016

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

510(k) Summary

Type of 510(k) Submission: **“Special 510(k): Device Modification”**

Submitter: *dms-service llc, 11845 W. Olympic Blvd, Ste 880W, Los Angeles, CA 90064*

Contact Person: *Lynda Cole, Manager, lc@lcoledms.com
ph: (855) 407-2824, direct ph: (775) 315-0660, fax: (800) 441-3437*

Trade Name: *myPatch®-s* Model #: *3000*

Legally Marketed Device: *myPatch® Ambulatory ECG Recorder, 510(k) K131190*

Classification: *21 CFR 870.2800, Medical Magnetic Tape Recorder, Cardiovascular Panel*

Device Class: *II* *Product Code: DSH* *Basis for Submission: Device Modification*

Description of the Modifications to the Legally Marketed Device:

The modifications of the device include the following:

1. Battery Change

The battery on the new device is a 3.7v 350mAh Lithium-Ion Polymer. The larger battery allows device to run for a longer period so the device can record up to 7 days.

2. Performance Specification

The device can record 1, 2 or 3 channels of ECG. The previous marketed device recorded 1 or 2 channels of ECG.

3. Electrode material change

We have offered an option of an electrode that uses a foam base instead of the PUR Film based material used in the previous electrode. Many customers prefer this material to the PUR film so we have designed one as another option for customers.

Both the myPatch®-s and myPatch® recorder the electrode will have the same socket connection as the electrode in the legally marketed 510(k).

There are no changes to the intended use of the device.

There are no changes to the fundamental scientific technology of the device.

Based on the information contained in this 510(k) notification and in design control activities, dms-service llc has determined that the myPatch®s device does not raise any new safety or effectiveness issues and is substantially equivalent to the legally marketed ambulatory ECG monitor, myPatch® that is currently in commercial distribution in the United States which has been determined to be substantially equivalent to devices in commercial distribution prior to May 26, 1976.

Device Description:

The myPatch®s ambulatory electrocardiograph (ECG) recorder is a small, lightweight monitor that records ECG continuously. The unit records 1, 2 or 3 channels of ECG up to 7 days. The device is composed of a large ECG electrode and an ECG recorder. The ECG recorder snaps onto the electrode and records until the recorder is removed from the electrode. At the end of the recording, the recorder can be plugged into a PC via a USB cable. The ECG recording can be transferred in an available file format that can be processed through recording processing software provided by recording processing software manufacturers and analyzed by qualified healthcare providers.

As the myPatch®s can be worn continuously up to 7 days it will be worn (used) in homes, healthcare facilities, hospitals, and where ever the patient may go.

The components that are part of the myPatch®s recorder are a lead wire, USB cable and the myPatch®s electrode. Per the 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 electrode connects to the myPatch®s and a list of features and specifications in tabular format.

The manufacturer, Berry Plastics, has tested the adhesives in the product in accordance with ISO 10993 and found them to be non-cytotoxic, non-irritating and non-sensitizing. In addition, they have provided us with the cytotoxicity report, irritation report and sensitization report for our Biocompatibility records. The electrodes have been tested to ANSI/AAMI EC12 and have passed all tests. The electrodes have been tested for shelf life and adhesive performance. The electrodes are not intended for use as sterile or for any radiographic, x-ray or MRI procedures. All labeling requirements have been met. By complying with this guidance before marketing our device the electrode is not subject to the premarket notification requirements of section 510(k).

The lead wire has been tested by the manufacturer to EN 55024:1998 +A1:2001 +A2:2003 and EN 55022:1998+A1:2000+A2:2003 standards. The copy of the Certificate of Conformity is in our files.

The myPatch®s records ECG in accordance to the standard IEC 60601-2-47:2012 for ambulatory ECG Recorders.

During the recording the patient wears the myPatch®s connected to an electrode on the upper sternum. The myPatch®s consists of a microprocessor, measuring circuit, memory, data storage, light-emitting diode (trans-illuminates the plastic casing), and contract to the electrode. In addition to that, myPatch®s contains firmware to control the collection of the ECG data and software to transfer to the processing software.

The battery is a rechargeable lithium polymer battery with a built-in protection circuit. The charge of the myPatch®s is by use of a USB cable which can only be connected to myPatch®s when it is not connected to the electrode. The myPatch®s device must be snapped onto the electrode to turn on and acquire data

myPatch®s has a serial number and product number in a bar code format and numbers to secure the traceability of the equipment and the data during and after the investigation. myPatch®s is reusable.

The electrode (accessory to myPatch®s) is the 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 placed on the underneath side of the adhesive tape. Through this electrode gel the ECG of the patient is measured. The top side of the electrode has the connector to the myPatch®s and one snap for an optional lead wire. The conductor paths are flex strips that run between the connector 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 torn off when placing the myPatch®s on the upper sternum. The electrode has to be connected to the myPatch®s to have any practical use. The electrode is a single use device and is disposed of after the one single use.

When recording a 3 channel ECG, a standard lead wire is attached to the snap on the front, bottom of the electrode. This lead wire attaches to any standard ECG electrode. The normal placement of this electrode is the V5 position.

Indications for Use:

myPatch®s 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 myPatch®s is intended for use by Adults and all Pediatric subgroups.

myPatch® 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 indications for use for the predicate myPatch® and the new myPatch®s are the same with the exception of the addition of the users. At the time of 510(k) of the predicate device there was no FDA guidance to delineate users based on age.

Intended Use

The myPatch®s ECG Recorder is a small digital Holter 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 myPatch®s ECG Recorder can record ECG up to 7 days on the torso of a patient through a myPatch®s-compatible ECG electrode (length or recording time is based on the sample rate and channel selection). The patient's ECG is recorded to the myPatch®s ECG Recorder and then transferred via the myPatch®s USB cable to a Holter analysis system for review by a physician or other qualified personnel. Due to the continual wearing of a Holter monitor, this is a medical device that is used both in professional healthcare facilities and also outside those facilities. This description meets the definition of a home use device. The myPatch®s is intended for use by adults and pediatrics. Not for use with infants weighing 10kg or less

Summary of Technological Characteristics:*Technological Characteristics:*

Technical Equivalence	myPatch®	myPatch®s	Similarities/Differences
Type of ECG Recorder	Patch	Patch	Same
Number of ECG Channels	1 or 2	1, 2 or 3	Different: The addition of the 3 rd channel brings the Patch style recorder more in line with the standard ambulatory Holter recorder. This is a feature many doctors have requested. This is an improvement in the device. There is no change to the safety and effectiveness of the device.
Wear Time	Up to 3 days	Up to 7 days	Different: More and more practitioners are requesting longer recording times from the ambulatory Holter recorders. In a 2013 Future Cardiology Report it was shown that the average time of a first symptomatic arrhythmia was 3.2 days. The battery in the myPatch® has been tested and runs up to 10.7 days. If we rate it down 20% (standard battery wear and tear), we can expect to get a minimum of 8.5 days of recording throughout the life of the myPatch®s. Thus we are comfortable in quoting a 7 day recording period. This is an improvement in the device. There is no change to the safety and effectiveness of the device.
Recording Format	Continuous	Continuous	Same. There is no change to the safety and effectiveness of the device.
Power Requirement	Lithium Polymer 3.7v, 250 mAh	Lithium Polymer 3.7v. 350 mAh	Similar: The battery is still a rechargeable 3.7v Lithium Polymer. The myPatch®s uses the 350 mAh battery to produce a longer recording time. There is no change to the safety and effectiveness of the device.
Dimensions	8.8 x 39.1 x 48mm	10 x 40 x 49 mm	Similar: The myPatch® is slightly larger than the myPatch®. There is no change to the safety and effectiveness of the device.
Weight	6 grams	7 grams	Similar: The myPatch®s is slightly heavier than the myPatch®. There is no change to the safety and effectiveness of the device.
Frequency Response	0.67Hz – 40 Hz	0.05Hz – 110Hz	Different: The myPatch®s has a frequency response more in line with AECG monitors. This is an improvement in the device. Reference: Braemar DL800 Freq Response (.05Hz – 60Hz), Braemar DL900 (.05Hz – 60Hz), NE Monitoring 153 (.05Hz – 70Hz), GE Seer (.05Hz – 40Hz) and Philips (.05Hz – 60Hz) There is no

			change to the safety and effectiveness of the device.
Input Impedance	>10MOhms	>10MOhms	Same. There is no change to the safety and effectiveness of the device.
Resolution	12 bits	12 bits	Same. There is no change to the safety and effectiveness of the device.
Performance Standard	Design Verification IEC 60601-2-47	Design Verification ECG 60601-2-47	Same. There is no change to the safety and effectiveness of the device.
Safety			
	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47	Same. There is no change to the safety and effectiveness of the device.
Biological Equivalence			
Medicinal Substances	n/a	n/a	Same. There is no change to the safety and effectiveness of the device.
Tissue	n/a	n/a	Same. There is no change to the safety and effectiveness of the device.
Blood Products	n/a	n/a	Same. There is no change to the safety and effectiveness of the device.
Body Fluids Contacted by Device	n/a	n/a	Same. There is no change to the safety and effectiveness of the device.
Type of Contact to Intact Skin	Non-invasive	Non-invasive	Same. There is no change to the safety and effectiveness of the device.
Mucosal Membrane Contact	n/a	n/a	Same. There is no change to the safety and effectiveness of the device.
Duration of Skin Contact	Up to 3 days	Up to 7 days	Different: The longer wear time means the electrode will be on skin for a longer period of time. This is an improvement in the device. There is no change to the safety and effectiveness of the device.
Sterile vs Non-Sterile	Non Sterile	Non Sterile	Same. There is no change to the safety and effectiveness of the device.
Biological Compatibility	ISO 10993-1	ISO 10993-1	Same. There is no change to the safety and effectiveness of the device.
Clinical Equivalence			
Medical Purpose	Ambulatory ECG	Ambulatory ECG	Same. There is no change to the safety and effectiveness of the device.
Single Use Patch	Reusable/Rechargeable Monitor, Single Use Electrode	Reusable/Rechargeable Monitor, Single Use Electrode	Same. There is no change to the safety and effectiveness of the device.
Recording Standard	Holter	Holter	Same. There is no change to the safety and effectiveness of the device.
Recording Format	Continuous	Continuous	Same. There is no change to the safety and effectiveness of the device.
Patch Placement	Sternum	Left Sternum	Similar: The new style electrode allows for recording Lead II, Lead III and V5. The myPatch® electrode had no specific leads to monitor. The ability to record Leads II and III and V5 keeping in line with a standard Holter recorder. This is an improvement in the design. There is no change to the safety and effectiveness of the device.
Recording Period	Up to 3 Days	Up to 7 Days	Different: More and more practitioners are requesting longer recording times from the ambulatory Holter recorders. In

			a 2013 Future Cardiology Report its was shown that the average time of a first symptomatic arrhythmia was 3.2 days. The battery in the myPatch® has been tested and runs up to 10.7 days. If we rate it down 20% (standard battery wear and tear), we can expect to get a minimum of 8.5 days of recording throughout the life of the myPatch®s. Thus we are comfortable in quoting a 7 day recording period. This is an improvement in the device. There is no change in the safety and effectiveness of the device.
New Safety & Effectiveness Issues	n/a	n/a	Same. There is no change in the safety and effectiveness of the device.

USABILITY TESTING:

Test Performed	myPatch® Result	myPatch@s Result	Same, Similar or Different
Usability: Device Description	Records ECG through a compatible electrode	Records ECG through a compatible electrode	Same
Usability: Software	Device contains embedded software appropriate for recording ECG, storing ECG and for charging.	Device contains embedded software appropriate for recording ECG, storing ECG and for charging.	Same
Usability: USB Cable	Device uses a USB cable to transfer the recorded file and to charge.	Device uses a USB cable to transfer the recorded file and to charge.	Same
Usability: Mode of Operation	Continuous	Continuous	Same
Usability: Battery	Internally powered, rechargeable 3.7v Lithium Ion battery	Internally powered, rechargeable 3.7v Lithium Ion battery	Same
Usability: Patient Environment	The wearing of the device and the electrode is all that is in the patient environment. The electrode covers the USB port so no connections can be made to the patient while wearing the device.	The wearing of the device and the electrode is all that is in the patient environment. The electrode covers the USB port so no connections can be made to the patient while wearing the device.	Same
Usability: Data Transfer	The data can only be transferred from the device using the USB cable.	The data can only be transferred from the device using the USB cable.	Same
Usability: LED Charge Lights	Three LED lights blink on the device while charging.	Three LED lights blink on the device while charging.	Same

Usability: LED Charged State	Three LED lights show solid when the device is charged.	Three LED lights show solid when the device is charged	Same
Usability: Malfunction Light	The device shows a red light if it has malfunctioned.	The device shows a red light if it has malfunctioned.	Same
Usability: Power Light	When connected to the electrode the user will see a solid green light. The light will then blink for 5 minutes.	When connected to the electrode the user will see a solid green light. The light will then blink for 5 minutes	Same
Usability: Connecting Device to Electrode	The device clicks into the socket (cup) that is on the electrode.	The device clicks into the socket (cup) that is on the electrode.	Same
Usability: Device Removal from Electrode	To remove the device from the electrode, snap tab on the bottom end of the socket (cup) and slide the device out of the electrode.	To remove the device from the electrode, snap tab on the bottom end of the socket (cup) and slide the device out of the electrode.	Same
Usability: Patient Environment	The device is not intended to modify the patient environment.	The device is not intended to modify the patient environment.	Same
Usability: Environment	The device is not intended to influence the environment	The device is not intended to influence the environment	Same
Usability: Battery	The lifetime of the battery restricts the shelf life of the device	The lifetime of the battery restricts the shelf life of the device	Same
Usability: Single use	The device is not intended for single use. The electrode is intended for single use.	The device is not intended for single use. The electrode is intended for single use.	Same
Usability: Alarm System	The device does not use an alarm system.	The device does not use an alarm system	Same
Usability: Device Classification	The device is classified as Body Worn.	The device is classified as Body Worn.	Same
Usability: Frequently Used Functions	Gripping/Holding, Charging, Cleaning, Disconnecting the device and electrode, removing device from electrode & patient, transferring recorded file, storing data	Gripping/Holding, Charging, Cleaning, Disconnecting the device and electrode, removing device from electrode & patient, transferring recorded file, storing data	Same

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:

There are 2 components of the device that have direct contact with the skin in the final form, the electrode gel and the electrode foam adhesive.

The manufacturer of the adhesive, Berry Plastics, has tested the adhesives used in the electrode in accordance with ISO 10993 and found them to be non-cytotoxic, non-irritating and non-sensitizing. In addition, they have provided us with the cytotoxicity report, irritation report and sensitization report for our Biocompatibility records.

Parker Labs, the manufacturer of the electrode gel, has cited claimed proprietary information of their product and has provided a letter to us stating that the biocompatibility testing has been performed and the gel has passed the tests. The actual test records are at Parker Labs and they have made them available to FDA inspectors.

Electrical safety and electromagnetic compatibility (EMC):

A CB test certificate has been provided by the battery manufacturer, EEMB(SZ) Co. Ltd. That battery was additionally evaluated to EN 62133(ed2) :2013.

EMC testing was performed by DANAK, an accredited testing board with international cooperation on accreditation. The testing is registered under certificate 19/14687. The testing found that the device was found to be in compliance with the specifications of IEC 60601-1-2:2007 (3rd edition) Clause 6.1 Emission and Clause 6.2 Immunity.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation has been 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 (5/11/2005)". The software for this device, per the FDA, is a moderate level of concern. The predicate was considered a "minor" level of concern as a malfunction of, or a latent design flaw in, the Software Device could not lead to an erroneous diagnosis and or a delay in delivery of appropriate medical care that would likely lead to a minor injury.

BENCH TESTING:

Linearity and dynamic range Test: (mp = myPatch® and mps=myPatch®s)

A 4Hz sine wave with an amplitude of .5 mV, 1 mV, 2 mV and 10 mV p-v into the ECG input channel. Offset = -300 and +300. It was confirmed that in the playback signal display the sine waves had a minimum amplitude p-v difference to the input signal of less than 10% or 50 µV, selecting the smallest value.

Common Mode Rejection Test:

The common mode rejection shall be at least 60dB for a sinusoidal signal at the supply mains frequency and at least 45 dB at twice the supply mains frequency. The common mode rejection capability is defined as the ration of the p-v value of the interfering supply mains frequency to the p-v value of the resulting signal in an ECG input channel, referred to input. The measured output during each tests period shall not exceed 4mV p-v.

myPatch®: Ch1, CMRR =20* log (4V@50Hz/124 µV) = 90dB

myPatch®s: Max CMMR 56/60Hz: CMRR=20* log (4V/450 µV) = 79dB

myPatch®s was tested at 1024Hz, the highest frequency sample speed. Outputs on both devices passed within a similar range. Substantially Equivalent

Input Impedance:

The myPatch®s was tested at the 1024HZ sample rate, which is the highest frequency sample speed. Outputs on both devices passed within a similar range. Substantially Equivalent.

Gain Accuracy:

Outputs on both devices passed within a similar range. Substantially Equivalent

Gain Stability:

Note: myPatch® test measured for 3 days & myPatch®s measured at different sampling rates up to 10 days.

Outputs on both devices passed within similar range. Substantially Equivalent.

System Noise:

myPatch®s tested in ranges of 16 μV – 30 μV on all 3 channels in all sample rates (128, 246, 512 and 1024). myPatch® tested at 21 μV . The outputs on both devices passes within similar range. Substantially equivalent.

Baseline Drift:

Both devices tested at 20 μV on all channels. myPatch® was tested for 3 days and myPatch®s tested over 10 days at 128 sample rate, 1 channel, 4.7 days at 256 sample rate, 3 channels and 3 days at 512 sample rate, 2 channels.

The outputs on the devices were the same. Substantially Equivalent.

Multi-channel Crosstalk:

myPatch® and myPatch®s behaved identically. While applying a 10Hz sine wave with an amplitude of 4mV p-v into only one ECG input channel (all other channels were shorted out), there was a flat line on the remaining 2 channels on myPatch®s (measuring at 25 μV). The myPatch® showed the same with the exception of only 1 channel showing a flat line.

The outputs on the devices were the same. Substantially Equivalent

Frequency Response:

The response of the myPatch® and myPatch®s to a 3mV 100ms rectangular pulse did not show a baseline amplitude displacement after the pulse of more than 0.1 mV referred to the baseline before the pulse. The slope outside the pulse was less than 0.3 mV/s. The leading edge overshoot was less than 10%.

The outputs on the devices were the same. Substantially Equivalent.

The amplitude response to sinusoidal signal tests were done with signals within the frequency range 0.50Hz to 110Hz (depending on sample rate) shall be between 140% and 70% (+3dB to -3dB) of the response at 5Hz.

Both devices passed in the appropriate ranges. Substantially Equivalent.

Responses to all pulses of a 1.5mV, 40ms triangular pulse train shall were within 70% to 110% of the maximum amplitude in a train of 1.5mV, 200ms triangular pulses. The lowest peak-to-base amplitude of the 1.5 mV, 40ms base width triangle pulse train was no less than 60% of the highest peak-to-base amplitude of the 1.5mV 200ms base width triangle pulse train.

The myPatch®s was tested at sample rates of 128, 256, 512 and 1024. All results from both units were within the range of 70% - 100%. Substantially equivalent.

Note: Test results are in ST Frequency Test Document

Timing Accuracy >24 hours:

The myPatch®s ran for full recording times at the different sample rates. All testing came in under 0.005% error. The myPatch® tested at 0.0057% error.

Results are nearly identical. Substantially equivalent.

Temporal Alignment:

For both the myPatch® and myPatch®s the results were the same. There was no skew of the rising and falling edges of the signal between each of the channels more than 20ms. The myPatch®s was tested at all sample rates.

Results are identical. Substantially equivalent.

Monitoring time:

The myPatch® recording testing confirmed that the recorder ran 72 hours. The myPatch®s recording testing confirmed the recorder ran 257 hours at 128 sample rate (single channel recording) , 114 hours at 256 sample rate (3 channels recorded), 98 hours at 512 sample rate (2 channels recorded) and 92 hours at 1024 sample rate (1 channel recorded).

These results are as expected. The recorders are designed to run for different time periods. Substantially Equivalent.

Data Retention:

Recordings were done on all sample rates of the myPatch®s recorder, the device was removed from the electrode and not downloaded for a minimum of 72 hours. Each test passed. The same test was done on the myPatch® recorder and it passed. Substantially Equivalent.

Note: To do all the bench tests listed above using different sample rates, it was necessary to change the software configuration in the management mode. The settings were as followed:

128Hz sample rate:	ECGFrontendFreq 1 ECGStorageFreq 0
256Hz sample rate:	ECGFrontEndFreq 1 ECGStorageFreq 1
512Hz sample rate:	ECGFrontEndFreq 2 ECGStorageFreq 2
1024Hz sample rate:	ECGFrontEndFreq 3 ECGStorgaeFreq 3
3 Channel	ECGElectrodeConfigCh1 10 ECGElectrodeConfigCh2 11 ECGElectrodeConfigCh3 13
2 Channel	ECGElectrodeConfigCh1 10 ECGElectrodeConfigCh2 11 ECGElectrodeConfigCh3 0

1 Channel ECGElectrodeConfigCh1 10
 ECGElectrodeConfigCh2 0
 ECGElectrodeConfigCh3 0

Recording Time MeasureDuration 20160 ; max 14 days (128Hz sample rate)
 MeasureDuration 10080 ; max 7 days (256Hz sample rate)
 MeasureDuration 7200 ; max 5 days (512/1024Hz sample rate)

FDA Recognized Standards for which myPatch®s Conforms to:

IEC 60601-1-2:2007 (3rd Edition) Clause 6.1 Emission, Clause 6.2 Immunity
 FDA Recognition # 19-1
 ISO 15223-1:2012 Symbols to be used with medical devices labels, labeling and information supplied
 FDA Recognition # 5-91
 IEC 62304:2006 Software Life Cycle Process
 FDA Recognition # 13-32
 IEC 60601-1-11:2010 Medical Electrical Equipment used in Home Healthcare Environment
 FDA Recognition #19-6
 IEC 60601-2-47 Edition 2.0 2012 Ambulatory Electrocardiographic Systems
 FDA Recognition # 3-128
 ANSI/AAMI EC12 “Disposable ECG Electrodes”
 FDA Recognition #3-52
 ISO 10993-1:2009 Part1, Biological Evaluation of Medical Devices, Evaluation & Testing within a risk management process
 FDA Recognition #2-156
 ISO 14971:2007 Applications of Risk Management to Medical Devices
 FDA Recognition # 5-70

Conclusions: 510(k) Substantial Equivalence Decision Making Process with myPatch® and myPatch®-s

Does myPatch®-s have the same indications for use statements? YES
 Does myPatch®-s have the same intended use and may be substantially equivalent? YES
 Does myPatch®-s have the same technological characteristics? YES
 Are the descriptive characteristics precise enough to ensure equivalence? YES
 Are performance data available to assess equivalence? YES
 Does the performance data demonstrate equivalence? YES

The affirmative answers to the questions above determine myPatch®-s is substantially equivalent to myPatch®.

The non-clinical data support the safety of the myPatch®s and the hardware and software verification and validation demonstrate that the myPatch®s device should perform as intended.