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

February 22, 2017

Dms-service LLC
Lynda Cole
Owner/manager
11845 W. Olympic Blvd
Ste 880W
Los Angeles, California 90064

Re: K163535
Trade/Device Name: myPatch®sl
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: January 20, 2017
Received: January 24, 2017

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.

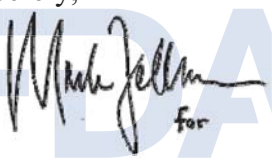
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K163535

Device Name
myPatch®sl

Indications for Use *(Describe)*
myPatch®sl 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®sl 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 K163535

1. *Submitter:*

Dms-service LLC 11845 W. Olympic Blvd, Ste 880W, Los Angeles, CA 90064

Primary Contact:

Lynda Cole (855) 407-2824, fax: (800) 441-3437, lcole@dms-service.com

2. *Product Names:*

Device Trade Name:	myPatch®sl
Common/ Usual Name:	Ambulatory ECG Recorder (Holter)
Classification:	Medical Magnetic Tape Recorder 21 CFR 870.2800 Product Code DSH Cardiovascular

3. *Predicate Device to Which This is Substantially Equivalent*

myPatch®s 510(k) 160704

4. *Device Description:*

The myPatch®sl (model # 3000sl) ambulatory electrocardiograph (ECG) recorder is a small, lightweight ambulatory ECG recorder that records ECG continuously. The unit records 1 or 2 channels of ECG up to 14 days and 3 channels up to 9 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 turned off or the battery is drained. At the end of the recording, the recorder can be plugged into a PC via a 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. Only the recorder is part of this 510(k) application.

The myPatch®sl recorder also incorporates an Event feature where the patient double taps on the recorder when they feel a symptom.

The myPatch®sl recorder has a power button on the recorder. Once depressed for 1 second, the green LED flashes. The LED will flash for 30 seconds as a “start-up” period. This gives the user time to apply the electrode to the patient’s sternum without recording artifact during the hookup period. To power off the recorder, the button is held down 2 seconds. A red light will flash and the recording period ends.

As the myPatch®sl is worn continuously up to 14 days it will be worn (used) in homes, healthcare facilities, hospitals, and where ever the patient may go.

The associated accessories that are part of the myPatch®-sl recorder are a lead wire, USB cable and the myPatch®-sl 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®sl and a list of features and specifications in tabular format.

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

During the recording the patient wears the myPatch®sl connected to an electrode on the upper sternum. The myPatch®sl consists of a microprocessor, recording circuit, memory, data storage, light-emitting diode (trans-illuminates the power button), and snap contacts to the electrode. In addition to that, myPatch®sl contains firmware to control the recording of the ECG data and software to transfer the recorded ECG file to the pc.

The battery is a rechargeable lithium polymer battery with a built-in protection circuit. The charge of the myPatch®sl is by use of a USB cable with a proprietary connector which can only be connected to myPatch®sl when it is not connected to the electrode.

The myPatch®sl 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 studies.

myPatch®sl is reusable.

The electrode (accessory to myPatch®sl) 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 recorded. The top side of the electrode has 4 snaps that will connect in only one way to the myPatch®sl 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®sl on the upper sternum. The electrode must be connected to the myPatch®sl 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.

The case of the myPatch®sl recorder is a Sabic/Lexan HP1 high flow polycarbonate for medical device applications and has the following certifications: ISO10993 or USP Class VI.

5. *Indications for Use*

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

6. *Intended Use*

The myPatch®-sl 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®-sl ECG Recorder can uses a rechargeable lithium polymer and can record ECG up to 14 days (2 channels) on the torso of a patient through a myPatch®-sl ECG electrode (length or recording time is based on the sample rate and channel selection). The patient's ECG is recorded to the myPatch®-sl ECG Recorder and then transferred via the myPatch®-sl USB data transfer cable to a Holter analysis system for review by 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 outside those facilities. This description meets the definition of a home use device. The myPatch®-sl is intended for use by adults and all pediatric sub-groups. 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 myPatch®-sl ECG Recorder.

7. Comparison of Technological Characteristics with the Predicate Device

Technological Characteristics:

Technical Equivalence	myPatch®s (Predicate)	myPatch®sl	Similarities/Differences
Type of ECG Recorder	Patch	Patch	Same
Number of ECG Channels	1or 2	1, 2 or 3	Same
Wear Time	Up to 7 days	Up to 14 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®sl has been tested and runs up to 17.6 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 myPatch®sl. Thus we are comfortable in quoting a 14 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 350 mAh	Lithium Polymer 3.7v 600 mAh	Similar: The battery is still a rechargeable 3.7v Lithium Polymer. The myPatch®sl uses the 600 mAh battery to produce a longer recording time. There is no change to the safety and effectiveness of the device.
Dimensions	10x 40 x 49mm	1.75”x 2” x .5”	Similar: The myPatch®sl is slightly larger than the myPatch®s. There is no change to the safety and effectiveness of the device.
Weight	17 grams	25 grams	Similar: The myPatch®sl is slightly heavier than the myPatch®s. There is no change to the safety and effectiveness of the device.
Frequency Response	0.05Hz – 110 Hz	0.05Hz – 175Hz	Similar. 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 7 days	Up to 14 days	Different: The longer wear time means the electrode will be on skin for a longer time. This is an improvement in the device. There is no change to the adhesives in the electrode. 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	Left Sternum	Left Sternum	Same There is no change to the safety and effectiveness of the device.
Recording Period	Up to 7 Days	Up to 14 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®sl has been tested and runs up to 17.6 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 myPatch®sl. Thus we are comfortable in quoting a 14 day recording period. This is an improvement in the device. There is no change to 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.

8. Performance Data
Determination of Substantial Equivalence – Non-clinical

The myPatch®sl was designed and tested for compliance with the applicable clauses of the following standards:

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 *General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-11:2015 *General requirements for basic safety and essential performance*

IEC 60601-2-47:2012 *Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*

IEC 62366:2007, IEC 62366:2007/AMD1:2014 *Application of usability engineering to medical devices*

IEC 62304:2006 (First Edition) + A1:2015 *Medical device software life cycle processes*

IEC60601-1:2005, IEC 60601-1:2005/AMD1:2012 Chapter 14 *PEMS*

IEC 62133:2012 Battery Safety Testing

IEC/EN 60601-1-2 (2015) *Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

ISO 15223-1:2012 *Symbols to be used with medical devices labels, labeling and information supplied*

ANSI/AAMI EC12 "*Disposable ECG Electrodes"*

The myPatch®sl has been designed and manufactured according to 21 CFR Part 820. The myPatch®sl has undergone software validation as well as performance verification and validation to ensure it meets all design inputs and performance requirements.

Biocompatibility Testing

The biocompatibility evaluation for the myPatch®sl electrode 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 (2009) and Part 12: Sample Preparation and Reference Materials (2012).

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). The software

was considered a Moderate Level of Concern as a design flaw or failure could directly result in minor injury to the patient or operator.

Usability Testing

The usability studies started May 25, 2016 and continued through the end of December, 2016. The Human Factors and Usability Engineering to Medical Devices guidance has been followed in tandem with IEC 62366:2007+A1:2014 “Application of usability to medical devices” and IEC 60601-1-6:2010+A1:2013 Usability.

There were 45 subjects that wore the electrode with the recorder during activities that included ocean swimming. 20 of the subjects were aged 11- 20 years. 25 subjects were 21 years to 59 years of age. No neonates were testing in ocean swimming environments.

There were 65 subjects that wore the electrode with the recorder performing daily activities that included showers. Ages in this group were 5 years of age to 75 years of age. Of this group 25 subjects were aged 5 years to 20 years and 40 subjects were over 20 years.

There were 25 subjects that wore the electrode with the recorder that included gym workouts of 35 minutes to 60 minutes, showers and normal daily activities. Ages in this group were 19 years of age to 59 years of age. There were 15 tests done on age group 2 months to 1 year of age in their daily environment that included baths.

Validation: The user wore the device for 2 weeks and had good signal while performing daily activities. Two week studies included 20 studies performed in age groups 6 years of age to 19 years of age and 20 studies in 21 years to 78 years of age. There have been 15 studies performed on ages 2 months to 1 year.

Mechanical Testing

The following tests were performed

4.11, Power input
5.7 Humidity preconditioning treatment (168hrs)
5.9.2.1 Accessible parts,
7.1.2 Legibility of markings
7.1.3 Durability of marking
8.7 Leakage current test
8.8.3 Dielectric voltage withstand
8.8.4.1 Ball pressure
8.5.5.1a Defibrillation-proof applied parts-Measurement of hazardous electrical energies
8.5.5.2 Defibrillation-Proof Applied Parts or Patient connection of Defibrillation
11.1.1 Temperature test
11.6.5 Ingress protection
11.6.6 Cleaning
13.1.2, Measurement of power
13.2 Single fault conditions
15.3.2 Push test

15.3.3 Impact test
15.3.4.1 Drop test
15.3.6 Mould stress
Simulated use testing

Risk Management

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

Clinical Studies

The subject of this premarket notification did not require clinical data to support substantial equivalence

9. Conclusions

The myPatch®sl is now able to store data from 2 channel ambulatory recordings for a maximum of 14 days when using a 128 sample rate whereas the predicate version, myPatch®s could only store data up to 7 days. Changes that were incorporated into the myPatch®sl included updated hardware/software components, a larger battery that is IEC 62133:2012 and UL certified and an IP rating of 68 for submersion up to 2 meters of water for 1 hour.

Dms-service LLC has determined these changes did not impact the safety and efficacy of the myPatch®sl recorder. The myPatch®sl recorder performance is substantially equivalent to the predicate device.