

510(k) Summary

March 26, 2013

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Submitter: dms-service llc, 2800 Neilson Way, Ste. 1, Santa Monica, CA 90405 Trade

Name: myPatch

Model #: Amors1000

Common Name: Ambulatory ECG Recorder

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

Device Class: II

Product Code: DSH

OCT 29 2013

Substantially Equivalent Devices

| Manufacturer | Substantially 510(k) equivalent devices | |
|----------------------------|--|---------|
| iRhythm | Zio Patch | K113862 |
| Cardiac Science Corp. | mySense Heart | K113176 |
| Scole Engineering Co. Inc. | Scole 300 | K923664 |

Device Description:

The myPatch ambulatory electrocardiograph (ECG) recorder is a small, lightweight monitor that records ECG continuously. The unit records 2 channels of ECG data up to 3 days. The device is composed of a large ECG electrode and ECG recorder. The ECG recorder clips 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 the USB connection. The ECG recording can be transferred in an available file that can be processed through recording processing software provided by recording processing software manufacturers and analyzed by qualified healthcare providers.

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

During the recording the patient wears the myPatch connected to an electrode on the sternum. The

myPatch consists of a plastic casing containing a battery and electronics consisting of a microprocessor, measuring circuit, memory, data storage, light-emitting diode (transilluminates the plastic casing), and contact to the electrode. In addition to that, myPatch contains firmware to control the collection of the ECG-data and software to transfer to processing software.

The battery is a rechargeable lithium polymer battery with a built-in protection circuit. The charging of the myPatch is by use of a USB cable, which can only be connected to myPatch when it is not connected to the electrode. At the bottom of myPatch is an electrical and click-on connection for the electrode. myPatch must be connected to the electrode to turn on and to acquire data. myPatch has a serial number to secure the traceability of the equipment and the data during and after the investigation. myPatch is reusable.

The electrode (accessory to myPatch,) 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 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 an electrical and click-on connection to myPatch. The conductor paths are printed on the adhesive tape. These conductor paths make the connection between the electrode gel on the underside and the connection to myPatch on the top side of the electrode.

Release liners are placed on the underside and on the top side of the electrode. These release liners cover the adhesive tape and the electrode gel and are torn off when placing the myPatch on the sternum. The electrode has to be connected to myPatch to have any practical use. The electrode is a single-use device and is disposed of after one single use.

Indications for Use:

The 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.

Technological Characteristics/Substantial Equivalence:

myPatch has the same technological characteristics as the ZioPatch, mySense Heart and Scio 300 ambulatory monitors. myPatch, mySense and ZioPatch are all patch based monitors. The Scio 300 and myPatch can both continuously record 2 channels of ECG data. All monitors are powered by a battery, the frequency response will not degrade the system performance and all monitors can record a minimum of 24 hours. myPatch will record up to 3 days and Zio Patch will record up to 14 days of continuous ECG.

All of the above mentioned devices are intended for the same use, recording continuous ECG signals. Any differences in the hardware design of the monitors and myPatch does not affect the safety or the effectiveness of the myPatch monitor. myPatch has met the design verification testing standards as set forth in IEC 60601-2-47, which is equivalent to ANSI/AAMI EC38.

Testing:

The myPatch ECG Recorder has undergone extensive testing, including testing listed below. All testing demonstrated acceptable results:

IEC 60601 1:2005 + CORR. 1 (2006) + CORR. 2 (2007) IEC 60601-1/A11:2011 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance same as IEC 60601-1:2012 ed 3.1 Consol. with am1

EN 60601-1-11: 2010 Medical electrical equipment - Part 1-11: 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 60601-2-47: 2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

EN 60601-1-2:2007 Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 62366:2008 Application of usability engineering to medical devices

EN 1041:2009 Information supplied by the manufacturer of medical devices

EN 980:2008 Symbols for use in the labeling of medical devices

EN 980 Bil.1:2008 CD-ROM Graphical symbols for use in the labeling of medical devices – Fact Sheet 1: Graphical symbols in electronic format

ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

The myPatch ECG Recorder has the CE Marking (CE 1008). The CE Mark is a statement that the myPatch ECG Recorder fulfills the guidelines established by the EU for medical devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 29, 2013

DMS-Service LLC
C/O Lynda Cole
2800 Neilson Way, Ste. 1
Santa Monica, CA 90405 US

Re: K131190
Trade/Device Name: MyPatch Amores 1000 Ambulatory ECG
Regulation Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph (ECG) Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: September 26, 2013
Received: September 27, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Earis -S

for

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

Enclosure

Indications for Use Statement

510(k)

Number: K131190

Device Name: myPatch

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Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.10.29
13:00:42-04'00'

