510(k) Summary for
HMicro Wired C-Patch Electrode
Page 1 of 2

Company name:	HMicro, Inc. 39355 California St. Ste 303, Fremont, CA 94538
Contact:	Kim Tompkins, VP Regulatory and Clinical Affairs Mobile: 408.981.4889 Email: kim@hmicro.com
Date prepared:	June 24, 2014
Trade Name:	HMicro Wired C-Patch Electrode, trade name subject to change
Common Name:	ECG Electrodes
Classification Name:	Electrocardiograph electrodes (21 CFR 870.2360, pro code DRX)
Class:	2
Panel Identification:	Cardiovascular
Predicate device:	3M Red Dot ECG electrodes (K000690, SE 5.17.2000)

Device description:

The HMicro Wired C-Patch Electrode is a single 3-inch patch electrode designed to be placed on the left upper chest or center chest and used for ECG monitoring. It is disposable and single use. It has five pre-wired electrodes affixed to a 3-inch silicone patch, where wires from the electrodes are pulled through the silicone patch for connecting into the patient monitoring cable.

Intended use:

The HMicro Wired C-Patch ECG Electrode is a single patient use, disposable, radiolucent wired ECG electrode with a silver/silver chloride sensing element designed for short-term, adult ECG monitoring at rest. It is designed to provide a single patch alternative to distributed electrodes. It has been tested using the GE Marquette Eagle 4000 ECG monitor and patient cable and should be used with monitors with equivalent or better sensitivity.

Substantial Equivalence:

The HMicro Wired C-Patch is similar to 3M Red Dot electrodes with respect to technological characteristics (see Table 1). Engineering justifications demonstrate substantial equivalence to the 3M Red Dot electrodes with respect to biocompatibility, electrical safety, and adhesion of patch to body performance. Shelf life testing demonstrated patch functionality through the sponsor requested expiration dating.

The key design difference between the subject and predicate device is that the subject device is a single 3 inch patch that is applied to the upper left or center chest and the predicate device is placed in the standard distributed configuration on the body (left arm, right arm, and left leg).

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An engineering study was completed to evaluate the usability of data from the subject and predicate device. Fifteen volunteers were enrolled and three tracings obtained: 3M electrodes, HMicro patch placed on the left chest and HMicro patch placed on the center chest. The study netted usable ECG tracings data from 13 volunteers for a total of 26 HMicro Wired C-Patches and 13 3M Red Dot electrode sets for evaluation. Eighty-five percent (11/13) of the volunteer data was similar between the two HMicro Patches and the respective control. For the two remaining volunteers, only one ECG tracing was usable--one for the control and the other for the HMicro Wired C-Patch. This study demonstrated that the HMicro is expected to provide usable ECG data as often as the commercially available predicate when used as indicated.

Table 1: Summary Comparison of Technological Characteristics--Subject and Predicate Devices

Characteristic	Predicate Device: 3M Red Dot	Subject Device: HMicro Wired C-Patch
Design	Pre-wired (radiolucent), hydrogel electrode, color coded, single use, non-sterile.	Pre-wired (radiolucent), hydrogel electrode, color coded affixed to 3 inch patch, single use, non-sterile.
Materials	Electrode backing includes a laminated conductive adhesive and silver/silver chloride sensing unit.	Electrode backing includes a laminated conductive adhesive and silver/silver chloride sensing unit; electrodes affixed to a 3 inch round silicone sheet patch using medical grade adhesives.
Energy source	The wires must be connected to an ECG patient cable which is in turn connected to an ECG monitor.	The wires must be connected to an ECG patient cable which is in turn connected to an ECG monitor.

Conclusion:

The HMicro Wired C-Patch is similar to the predicate 3M Red Dot electrodes predicate with respect to design, materials and energy source and as such is substantially equivalent.

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

July 24, 2014

HMicro, Inc.
Kim Tompkins
VP Regulatory/Clinical
39355 California St. Ste 303
Fremont, CA 94538

Re: K140096
Trade/Device Name: Wired C-Patch EKG Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II
Product Code: DRX
Dated: June 25, 2014
Received: June 26, 2014

Dear Ms. Kim Tompkins,

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.

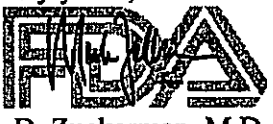
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

510(k) Number (if known): _K140096_____

Device Name:

Indications for Use:

The HMicro, Inc. Wired C-Patch is indicated for ECG monitoring of adults at rest when the upper left chest or center chest is available to place the patch.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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