510(K) Summary K101576

July 17, 2010

510(K) Owner and Submitter:
Team Innovations, Inc.
2521 S. 98th Street
West Allis, WI 53227

JUL 22 2010

Phone Number: 262-617-6980
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Principal point of contact: Mark Tiegs
Direct Phone Number for Mark Tiegs: 262-617-6980

This 510(K) submission is for:

Trade Name: CenterRidge Diagnostic ECG Electrode, and
CenterRidge Monitoring ECG Electrode
Common Name: Electrocardiograph (ECG) electrode
Class II device
Classification panel 74
Product Code DRX
Regulation number 870.2360

Team Innovations claims that the CenterRidge electrodes are substantially equivalent to several predicate legally marketed devices:

- 3M Health Care, Red Dot Resting EKG Electrode, catalog number 2330 covered by 510(K) number K932454, and
- Bio-Detek, Inc., Trace Rite Solid Gel ECG Electrodes, part numbers DE1070, LT301SG(PSG), LT401SG(PSG) and LT601SG(PSG), covered by 510(K) number K964213.

The CenterRidge ECG Electrodes are non-traditional tab electrodes, capable of diagnostic or monitoring use, depending on materials used in construction, and are intended to acquire ECG signals from the surface of the body. Both the CenterRidge Diagnostic ECG Electrode and CenterRidge Monitoring ECG Electrode are of multi-layer construction, using medical grade foam or cloth backing material, a silver/silver chloride coated sensing element and solid hydrogel. The raw materials used in the CenterRidge Electrodes are equivalent to the materials used in the predicate legally marketed ECG electrodes specified above. The intended patient population is adult and

pediatric. The skin surface contact area and proportional electrode size will be adjusted to fit the specific procedure and patient population.

The primary difference between the CenterRidge Electrodes and the predicate devices are geometry and shape. The 3M Health Care model 2330 and the Bio-Detek model DE1070 are traditional tab electrodes with a tab sensing element located on the perimeter of the electrode, whereas the Team Innovation CenterRidge electrode has the sensing element located within the body of the electrode. The internal location of the CenterRidge sensing element emulates the snap on the Bio-Detek models LT301SG(PSG), LT401SG(PSG) and LT401SG(PSG).

The CenterRidge electrodes were subjected to non-clinical, bench testing for electromagnetic compatibility conformance to the industry standard ANSI/AAMI EC12:2000/(R)2005. The CenterRidge electrodes passed all electrical performance tests per the ANSI/AAMI EC12:2000/(R)2005 standard. The CenterRidge electrodes were not clinically tested. Based on the CenterRidge electrodes satisfactorily passing all electrical compatibility tests and conforming to ANSI/AAMI EC12:2000/(R)2005, the CenterRidge ECG Electrodes are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Team Innovations, Inc.
c/o Mr. Mark D. Tiegs
VP & General Manager
2521 South 98th Street
West Allis, Wisconsin 53227

JUL 2 2 2010

Re: K101576
Trade/Device Name: CenterRidge Diagnostic ECG Electrode; and, CenterRidge Monitoring ECG Electrode
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrodes
Regulatory Class: Class II (Two)
Product Code: DRX
Dated: June 1, 2010
Received: June 7, 2010

Dear Mr. Tiegs:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

TEAM innovations

Indication for Use K101576

510(k) Number K101576:

Device Name: CenterRidge Diagnostic ECG Electrode, and
CenterRidge Monitoring ECG Electrode

Indication For Use:

The subject devices are ECG surface electrodes and will be manufactured in two configurations: one for diagnostic ECG use (CenterRidge Diagnostic ECG Electrode) and one for monitoring ECG use (CenterRidge Monitoring ECG Electrode).

The CenterRidge Diagnostic ECG Electrode is a diagnostic, single use (single patient), disposable ECG electrode. This electrode is intended to acquire ECG signals from the surface of the body. The intended population is adults and pediatrics. The intended duration of body contact is less than 24 hours.

The CenterRidge Monitoring ECG Electrode is a monitoring, single use (single patient), disposable ECG electrode. This electrode is intended to acquire ECG signals from the surface of the body. The intended population is adults and pediatrics. The intended duration of body contact is greater than 24 hours but less than 30 days.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101576

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