510(k) Summary

Monebo CardioBelt™ Electrode Belt

MAR 2 3 2007

K 063044

Submitter: Monebo Technologies, Inc
1800 Barton Creek Blvd
Austin, TX 78735-1606
Telephone: 512.732.0235
Facsimile: 512.732.0285
Contact person: Dale J. Misczynski
President and CEO

Date of Preparation: October 2, 2006

Device Name: Proprietary Name: *CardioBelt*™ Electrode Belt
Common Name: Electrocardiograph Electrode
Classification Name: Electrocardiograph Electrode

Regulatory Classification:
Class: II, 21 CFR 870.2360
Medical Specialty Panel: Cardiovascular
Product Code: 74 DRX

Devices to Which Substantial Equivalence is Claimed:

Device Name: *AccuHeartTm* Electrode Belt
510(k) Number: K043361
Device Name: Medi-Trace 200 and Medi-Trace 200-30 ECG Electrodes
510(k) Number: K960968
Device Name: CardGuard CG-2211 SelfChek
510(k) Number: K012223

Device Description:

The Monebo CardioBelt™ is a reusable electrode system consisting of an electrode assembly, an elastic chest belt, and an electronics package containing a Bluetooth transceiver. The CardioBelt™ electrodes are positioned against the patient's skin with light pressure, using the elastic chest belt. The CardioBelt™ is designed to be used without electrolytic gels and without adhesives on unprepared skin; that is without the requirements for shaving, abrading, or other skin preparation. The CardioBelt transmits ECG information to a compatible Bluetooth – enabled device. The CardioBelt contains a class II Bluetooth radio with a range of approximately 30 feet (spherical range).

The CardioBelt™ is powered by a rechargeable lithium ion battery. The electronics package must be physically separated from the electrode belt to charge the battery.

Intended Use:

The CardioBelt™ is a reusable electrode system intended for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. The CardioBelt™ is compatible for use with Bluetooth equipped ECG instruments capable of receiving Bluetooth™ Serial Port Protocol.

Functional and Safety Testing:

Monebo's CardioBelt™ has successfully undergone both bench and clinical testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate device.

The CardioBelt™ was tested and verified in accordance with 3510-0002-01 Rev1 CardioBelt Verification and Validation test plan. The following is a summary of the testing performed on the device. Specific test records can be found in the Monebo Document Control center.

The system risk assessment 8024-0002-00Rev1 was performed and the device was characterized as a moderate level of concern. The system safety and risk analysis conducted for the CardioBelt provided a rigorous design and structural evaluation aimed at identifing potential failures or possible system flaws which could directly or indirectly affect the patient. The device is a single lead acquisition system that transmits ECG data via Bluetooth™ communication to a generic Bluetooth™ recording and/or analysis system. The device does not perform ECG analysis.

Engineering and Verification Testing:

Engineering testing was performed to test compliance with the system requirements and risk assessment documents. Supporting test reports can be found in the Monebo Document control center. The tests were performed in accordance with EC38, EN60601-1 and EN60601-2-27. The device is classified as a Type 3 device using the EC38 1.2 c type definition. The device biocompatibility was evaluated and found to be satisfactory. 8051-0002-01 Rev-1tracability matrix was developed to track the verification of the system requirements 8012-0002-00 and hazard mitigations. The testing was conducted per EC38 test methods and the tests include:

Common Mode Rejection Tests
Frequency Response Tests
Input Dynamic Range Tests
Overall System Error Tests
Step Response Tests
System Noise Tests
Battery Life Tests
Communication Test

External Testing and Certification:

Third party testing was performed to assess compliance for Electromagnetic Compatibility, Medical Equipment General Safety requirements and Essential performance requirements for ECG devices.

EMC Testing Laboratories, Inc was used to determine compliance with:

EN301-489-1	ERM and EMC for Radio Equipment and Services
EN301-489-17	EMC for 2.4Ghz Radio Equipment EMC
EN61000-4-2	Electrostatic Discharge Testing
EN61000-4-3	Radiated Electromagnetic Fields
EN61000-4-11	Voltage Dips, Short Interrupts and Voltage Variations
CISPR22	Measurements of Radio Frequency Interference
EN55022	Radio Frequency Interference for Information Technology
EN61000-3-2	Limits of harmonic current emissions
EN61000-3-3	Limitation of voltage fluctuations and flicker in low voltage supply systems
EN60601-1	Medical electrical equipment - Part 1: General requirements for safety
EN60601-2-27	Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

High and low Temperature Tests
Leakage Current Tests
Dielectric Strength Tests
Safe Current Tests
Ingress of Liquid Tests
EMC and Immunity Tests
Mechanical Shock Tests

Third party verification reports are included with this submission and can be found in the Monebo Document Control Center. The reports indicate compliance with the general safety standards and with EN60601-1 and EN60601-2-27 ECG standards mentioned above.

Validation

Validation was conducted in accordance with 3510-0002-00 Rev 1 Verification and Validation test plan. The device and manual were evaluated for safety and clinical utility. The validation report can be found in the Monebo document control center. The report indicates that the device meets the clinical requirements and that the documentation is sufficient for operating the device in a clinical or home care environment. A white paper is included for review. The white paper was generated from a study at Bad Oeynhausen Herzzentrum hospital in Germany. The study compared the performance of the single lead Cardiobelt to a 12 lead ECG (Gold Standard). The CardioBelt was found to be easy to use and useful for ambulatory monitoring and as a screening tool to determine normal or pathologic ECG's.

Conclusions

Based on verification and validation testing the unit was found to meet the generally accepted safety testing requirements for an EC38 1.2 c type 3 ECG device. The device has a moderate level of concern based on the risk assessment 8024-0002-00. The Cardiobelt constitutes a safe and reliable means for transmitting ECG data. Its material composition and operation present no adverse health effect or safety risks to patients when used as intended.

Monebo's CardioBelt is substantially equivalent to the AccuHeart Electrode Belt.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2007

Monebo Technologies Inc.
c/o Dale J. Misczynski
President and CEO
1800 Barton Creek Blvd.
Austin, TX 78735-1606

Re: K063044
Trade/Device Name: CardioBelt Electrode Belt
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: Class II
Product Code: DRX
Dated: March 16, 2007
Received: March 19, 2007

Dear Mr. Misczynski:

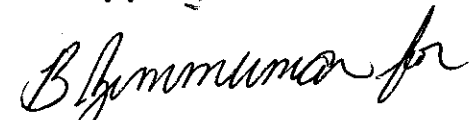
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Applicant: Monebo Technologies, Inc

510(k) Number (if known) K063044

Device Name: Monebo CardioBelt™ Electrode Belt

Indications for Use:

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Prescription Use ___X___ OR Over –the Counter _____

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063044