K090895

Section 5

AUG 2 6 2009

510(k) Summary

[As Required by 21 CFR 807.92]

Date Prepared: Mar. 27, 2009

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Trade Name: EKG-PLUS II Software
Common Name: ECG Analysis System
Classification Name: ECG Analysis System, product code LOS
Predicate Device: CARDIOVIEW ECG Interpretive Software (K974352)

Device Description:
The EKG-PLUS II Software is a program which receives, displays, stores and prints out in network environment the ECG data monitored, recorded and analyzed by a Bionet's ECG device.

Intended use:
EKG-PLUS II Software is a Windows-based program intended to receive, display, store and print out in network environment the ECG data monitored, recorded and analyzed by a Bionet's ECG device– CardioCare-2000 (Formerly, CardioCare EKG-2000) or CardioTouch-3000. The software can also store the ECG data as JPEG file.

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Non-clinical tests:

The performance of the EKG-PLUS II Software was comprehensively tested with the CardioCare-2000 and CardioTouch-3000. All functions as defined in the specifications were completely verified and validated.

The EKG-PLUS II Software adheres to the following FDA CDRH guidance:
CDRH Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, ODE, May 11, 2005

Conclusions:

The EKG-PLUS II Software is safe, as effective, and performs as well as the CARDIOVIEW ECG Interpretive Software. Accordingly, the EKG-PLUS II Software is substantially equivalent to the CARDIOVIES ECG Interpretive Software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 6 2009

Bionet Co., Ltd.
c/o Mr. H.L. Jung
MI Consulting Co., Ltd.
RM 431
Life Officetel, 61-3
Yoido-dong, Youngdeungpo-gu
Seoul, 150-731, Republic of Korea

Re: K090895
Trade/Device Name: EKG-PLUS II Software
Regulation Number: Unclassified
Regulation Name: ECG Analysis System
Regulatory Class: Unclassified
Product Code: LOS
Dated: August 4, 2009
Received: August 10, 2009

Dear Mr. Jung:

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,

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

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K090895

Device Name: EKG-PLUS II Software

Indications For Use:

EKG-PLUS II Software is a Window-based program intended to receive, display, store and print out in network environment the ECG data monitored, recorded and analyzed by a Bionet's ECG device– CardioCare-2000 (Formerly, CardioCare EKG-2000) or CardioTouch-3000. The software can also store the ECG data as JPEG file.

Prescription Use X AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090895