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510(k) SUMMARY
(21 C.F.R. 807.92)

1. Submitter Identification:

LEE & XIAO
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San Marino, CA 91108
Telephone: (626) 799-0998

DEC 11 2008

Contact Person: Yingchao Xiao, Esq.

Date: November 28, 2008

2. Device Name:

Trade Name: Bionet BM3Plus Patient Monitor
Common Name: Multifunctional patient monitor
Classification Name: Monitor, Physiological, Patient

3. Predicate Device:

Goldway UT4000F Patient Monitor (K021154)

4. Device Description:

Bionet BM3Plus Patient Monitor ("BM3Plus" or the "subject device") is a multifunctional device that monitors vital signs of human patients from neonates to adults. Parameters monitored by BM3Plus include electrocardiogram (ECG), pulse oximetry (SpO_2), pulse rate, noninvasive blood pressure (NIBP), temperature, and respiration. Data output is displayed in numeric and/or wave form(s) on a 7-inch color LCD screen. Selected parameters and waves can also be shown in print via a built-in 58 mm thermal printer. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits.

BM3Plus is compact and can be used in either stationary mode or on the move in all professional medical facilities. Its energy source can come from AC input or lithium-ion battery. BM3Plus' LAN connection capability enables the device to be built into a monitoring system, so that one person can monitor several patients at a time.

5. Statement of Intended Use:

The patient monitor is intended for use by trained healthcare personnel to diagnose and monitor multiple physiological parameters of human patients. It can be used on patients from adults to neonates. The device is designed as a bedside and portable monitor that can operate in all professional medical facilities.

Physiological data include but are not restricted to: electrocardiogram, pulse oximetry, pulse rate, noninvasive blood pressure, temperature, and respiration. The data output is displayed on an LCD screen and/or through a built-in printer as numerical data or in waveform. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits.

The patient monitor is not intended for use as an apnea monitor. The patient monitor is not intended for use during MRI or CT scans.

6. Comparison with Predicate Device:

Both BM3Plus and UT4000F are designed to monitor basic physiological parameters of human patients from neonates to adults. The predicate and the subject devices both monitor ECG, SpO_2, pulse rate, NIBP, temperature, and respiration. The predicate device can also monitor, as optional functions, invasive blood pressure and carbon dioxide, which are absent on the subject device.

In addition, the subject and the predicate devices use similar technologies and have little difference in terms of their functional specifications, conformation to consensus standards, energy use, biocompatibility, mechanics, or environment for use. Where differences do exist between the subject device and the predicate devices, those adaptations comply with relevant recognized consensus standards and do not affect the safety or effectiveness of BM3Plus. The differences include, but not limited to, BM3Plus', LAN output, Li-ion battery use, and compact design. These adaptations enhance the performances of the subject device yet do not interfere with its safety or effectiveness.

7. Testing:

BM3Plus meets the following recognized consensus standards:

- IEC 60601-1 (1988-12) + A1(1993) + A2(1995)
- IEC 60601-1-2 (2001)
- IEC 60601-1-4 (1999-10)
- IEC 60601-2-27 (1994-04)
- IEC 60601-2-30 (1999-12), EN 60601-2-30(2000)
- IEC 60601-2-49 (2001-07), EN60601-2-49(2001)
- EN 12470-4 (2001)
- EN 865 (1997)
- EN 1060-1(1995-12), EN 1060-3 (1997-9)

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- ISO 14971-1 (1998-10)

Clinical test is not applicable to BM3Plus.

8. Conclusion:

BM3Plus and UT4000F have the same intended use and have no major technological difference. In addition, where BM3Plus differs from UT4000F, the differences do not affect the safety or effectiveness of BM3Plus. Therefore, according to the principles FDA 510(k) notification, the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2008

Bionet Co., Ltd.
c/o Lee & Xiao
Mr. Yingchao Xiao
2600 Mission St., Suite 100
San Marino, California 91108

Re: K082008
Trade/Device Name: Bionet BM3Plus Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: November 5, 2008
Received: November 10, 2008

Dear Mr. Xiao:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

K082008

INDICATIONS FOR USE
(v.2)

510(k) Number (if known): K082008

Device Name: Bionet BM3Plus Patient Monitor

Indications for Use:

The patient monitor is intended for use by trained healthcare personnel to diagnose and monitor multiple physiological parameters of human patients. It can be used on patients from adults to neonates. The device is designed as a bedside and portable monitor that can operate in all professional medical facilities.

Physiological data include but are not restricted to: electrocardiogram, pulse oximetry, pulse rate, noninvasive blood pressure, temperature, and respiration. The data output is displayed on an LCD screen and/or through a built-in printer as numerical data or in waveform. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits.

The patient monitor is not intended for use as an apnea monitor. The patient monitor is not intended for use during MRI or CT scans.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B. Beckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082008