K052603

BL Healthcare

FEB 1 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92

Submitter: Michael Mathur
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Contact Person: Michael Mathur
President and CEO
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Date Prepared: 18 Apr 05

Trade Name: Telephone based BL Healthcare Remote Care Management System
Common Name: Telemedicine systems

Regulation Number: 870.2910, DRG
Regulatory Status: Class II

Predicate Devices:
BL Healthcare Remote Care Management Systems, K051470
Carematix Modified System, K040966
Zymed EasyView telemetry system (K001308)
Motion Media Care Station 126S Videophone (K031863)

Submission Device Description and Intended use:

Telephone based BL Healthcare Remote Care Management system serves as the communication link between compatible devices and the server software at a compatible healthcare facility. The purpose of the system is to collect and transmit patient vital signs and other physiological data and transmit these results to their healthcare provider at another facility. The healthcare provider is able to access the data for retrospective review and monitoring.

Substantial Equivalence Discussion

The submission device substantially equivalent to the BL Healthcare Remote Care Management System (K) With respect to Pulse Oximetry, substantial equivalence is claimed to Zymed EasyView telemetry system (K001308) and Care Station 126S Videophone

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(K031863). The Carematix Modified System supports monitoring of Peak Flow and Oxygen levels, weight, blood pressure, blood glucose and spirometer similar to the submission device.

Non-clinical testing

Substantial equivalence testing demonstrated with objective evidence that the functionality of the Telephone based BL Healthcare Remote Care Management system is substantially equivalent to those of the predicate devices.

Conclusion:
Analysis of the substantial equivalence testing concluded that that the BL Healthcare Remote Care Management system is substantially equivalent to the predicate devices. The BL Healthcare Remote Care Management system does not alter the measurement technology or the intended use of these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

BL Healthcare, Inc.
c/o Mr. Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Rd.
Newtown, CT 06470

Re: K052608
Trade Name: Telephone based BL Healthcare Remote Care Management System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: January 12, 2006
Received: January 17, 2006

Dear Mr. Borsai:

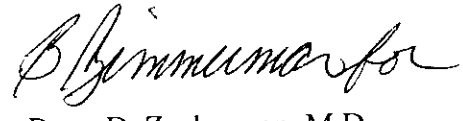
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0210. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

BL Healthcare

Indications for Use

510(k) Number (if known): K052608
Device Name: Telephone based BL Healthcare Remote Care Management System (RCMS)

Indications for Use

The purpose of the Telephone based BL Healthcare Remote Care Management System is to collect and transmit medical information such as weight, blood pressure and pulse rate, blood glucose, SPO2, FEV1 and PEF from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.

This system is installed by or with support from trained professionals.

This device is not intended to provide time sensitive data or alarms. This system may not be used as a substitute for direct medical intervention or emergency care. Interpretation of the information collected and transmitted requires clinical judgement by an experienced medical professional.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052608