BL Healthcare Inc

DEC 2 1 2011

K113493

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: 22 Nov 2011

Device Information
Trade Name: TCx-I Remote Care Management system
Common Name: Telemedicine systems
Classification Product Codes: DRG, DXN, NBW, LFR, BZH, DQA, DQD, FLL, GJS

Legally Marketed Predicate Device(s):
TCx-I Remote Care Management System (K101078)

Submission Device Description:
TCx-I Remote Care Management system collects and transmits measurement information such as weight, blood pressure and pulse rate, and Blood Glucose data from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.

Intended use and indications for use:
The purpose of the system is to collect and transmit medical information such as weight, blood pressure and pulse rate, and Blood Glucose data from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.

Summary of nonclinical testing
Software verification and validation was performed on the device to ensure that the product requirements were met. Electrical safety and Electromagnetic compatibility tests were performed on the device to ensure conformance to FDA recognized standards.

Substantial Equivalence Summary
The TCx-I Remote Care Management system has the same fundamental technology as the predicate device.

Conclusion:

The TCx-I system is substantially equivalent to the predicate device.

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

DEC 2 1 2011

BL Healthcare Inc, Inc.
c/o Mr. Michael Mathur
President & CEO
33 Commercial Street, Suite #3
Foxboro, MA 02035

Re: K113493
Trade/Device Name: TCx-I Remote Care Management System
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: II (two)
Product Codes: DRG, DXN, NBW, LFR, BZH, DQA, FLL, GJS, DQD
Dated: November 22, 2011
Received: November 25, 2011

Dear Mr. Mathur:

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

BL Healthcare Inc

Statement of Indication of Use K113493

The purpose of the TCx-I Remote Care Management System is to collect and transmit medical information such as weight, blood pressure and pulse rate, and blood glucose and other devices from the patients on completion of their testing and transmit these results to their healthcare provider at another facility. The system supports videoconferencing, multimedia education and messages.

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_____X_____ 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)

for Bram Zuckerman
Director DCD
(Division Sign-Off)
Division of Cardiovascular Devices

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