BL Healthcare Inc K101078

MAY 10 2010

12.0 510(k) Summary

1 Submitter's name, address, telephone number, contact person and date

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

Submitter's Name: Michael Mathur
Address, telephone number, contact person and date:
BL Healthcare, Inc
33 Commercial Street, Suite #3
Foxboro, MA 02035
Telephone number: (508) 543-4150 Fax: (508) 543-6150
Contact person: Michael Mathur
President and CEO, BL Healthcare, Inc.
mmathur@BLHealthcare.com
Date: 15 Apr 2010

2. Name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name if known:
Trade Name: TCx-I Remote Care Management system
Common Name: Telemedicine systems, Remote Healthcare System, eHealth device

3. Legally Marketed Predicate Device(s):
Telephone Based TCx-I Remote Care Management system (RCMS) **(K052608)**
TCx-I Remote Care Management system **(K051470)**
TCx-I Remote Care Management System **(K093379)**
RNK Telephonic Stethoscope Model TR-1 **(K034046)**
Carematix Wellness System **(K073038)**

4. 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.

5. A statement of 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.

6. If the device has the same or different technological characteristics as compared to the predicate device.

The TCx-I Remote Care Management system has the same fundamental technology as the predicate devices.

6. (b) An assessment of performance data.
6. (b) (1) non-clinical tests

- Non clinical substantial equivalency testing and Risk based verification testing was performed based on FDA guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" to ensure that the data is collected and transmitted correctly to the server.
- The device conforms to FDA recognized standards IEC60601-1-1 and IEC60601-1-2.
- Labeling was written in accordance with FDA's guidance "Guidance on Medical Device Patient labeling" April 19, 2001.

6. (b)(2) Assessment of the clinical tests submitted
No clinical tests were performed as part of the testing.

6. (b)(3) Conclusions drawn from non-clinical and clinical tests that demonstrate that the device is as safe and effective as the predicate device.
In conclusion, the non-clinical testing performed on the TCx-I Remote Care Management System met the required objective, it demonstrated that the device is as safe and effective as the predicate device. In addition, the TCx-I Remote Care Management System has the same fundamental technology as the predicate devices and therefore it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

MAY 10 2010

Re: K101078
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 Code: 74 DRG
Dated: April 13, 2010
Received: April 19, 2010

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.

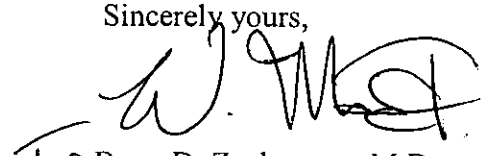
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

11.0 Indication for Use K101078

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 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 judgment 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101078

1 of 1