K051470
P1/5

BL Healthcare

JUN 8 - 2005

510(k) Summary

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

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Date Prepared: 18 Apr 05

Device Information
Trade Name: BL Healthcare Remote Care Management system
Common Name: Telemedicine systems

The BL Healthcare Remote Care Management system

Classification Names:

Regulation Number	Product Code	Classification Name	Devices supported by the system	Device 510(k) Number
870.2910	DRG	Physiological Signal Transmitters And Receivers		
870.1130	DXN	System, measurement, blood-pressure, non-invasive	A&D Medical (Lifesource) Model # UA 767PC	K982481
870.2720	FRW	Patient Scale	A&D Medical (Lifesource)	Exempt per 880.2700
862.1345	NBW	Glucose test system.	Roche Accu-Chek Compact system	K022171 K004010

Predicate Device(s):
The BL Healthcare Remote Care Management system is substantially equivalent in functionality to the following predicate device(s):

M3810a Philips Telemonitoring system, **K023749**
Carematix Wellness system, **K031840**
Carematix Wellness system, **K040966**
AvidCare Series 100 Telemanagement System, **K011779**
AvidCare Corporation Home Health Monitoring System, **K010029**
Aviva Systems, **K981533**

Submission Device Description:
BL Healthcare Remote Care Management system serves as the communication link between FDA approved compatible devices such as Blood Pressure monitor, Blood Glucose Instrument and Weight Scale, and the server software at a compatible healthcare facility. The healthcare facility may include healthcare provider, other caregivers, or a disease management center. The system enables video conferencing over broadband and a TV Interface between the Healthcare provider and the patient. The Healthcare provider may also enable video clips, automatic medication reminders and other training materials for the user to view. The TV interface provides this information on a specific TV channel and the user is informed of new updates or videoconferencing request via audio-visual indicators on the TV Interface remote.

The purpose of the system is to collect and transmit measurement 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.

Intended use and indications for use:
The purpose of the **BL Healthcare 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.

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.

Interpretation of the information collected and transmitted requires clinical judgement by an experienced medical professional.

Substantial Equivalence Comparison

Feature	Avid Care K011779 and K023749	Philips K030419	American Telecare AVIVA SYSTEMS MODEL NUMBERS 1010, 2020 K981533	Carematix Modified System K040966	BL Healthcare Remote Care Management system
Indications of use	Enable healthcare Providers to Manage chronic Conditions of patients remotely.	Enable healthcare Providers to Manage chronic Conditions of patients remotely.	Enable healthcare Providers to Manage chronic Conditions of patients remotely.	Enable healthcare Providers to Manage chronic Conditions of patients remotely.	Enable healthcare Providers to Manage chronic Conditions of patients remotely.
Intended use	Telemedicine System	Telemedicine System	Telemedicine System	Telemedicine System	Telemedicine System
Intended Users	Home users	Home users	Home users	Home users	Home users
Site of Use	Home; clinic	Home; clinic	Home; clinic	Home; clinic	Home; clinic
Data Collection software	Proprietary Software	Proprietary Software	Proprietary Software	Proprietary Software	Proprietary Software
Communication method with Remote Care Management System	Via modem over telephone line	Via modem over telephone line	Via modem over telephone line	Via modem over telephone line	Broadband Internet connection
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Blood Pressure Weight Glucose levels Oxygen saturation PT/INR FEV/PEF	Blood Pressure Weight Glucose levels Oxygen saturation PT/INR FEV/PEF	Blood Pressure Weight Glucose levels Oxygen saturation PT/INR Temperature	Blood Pressure Weight Glucose levels Oxygen saturation PT/INR FEV/PEF	Blood Pressure Weight Glucose levels
Implementation-method of collecting clearance by data from sensors	Modify off the shelf sensors with previous 510(k) approval by adding communicatio ns interface without altering the sensors	Modify off the shelf sensors with previous 510(k) approval by adding communications interface without altering the sensors	Modify off the shelf sensors with previous 510(k) approval by adding communications interface without altering the sensors	Modify off the shelf sensors with previous 510(k) approval by adding communications interface without altering the sensors	External communication device
Sensor Software	Unchanged	Unchanged	Unchanged	Unchanged	Unchanged
Connectivity	Wired to hub	Wired or	Wired to hub	Wireless to hub	Wireless to hub

		wireless to hub			
Communication method of hub with devices	Wired over serial port	Wireless RF protocol	Wireless RF protocol	Wireless RF protocol	Wireless RF protocol
Communications protocol	Proprietary	Proprietary	Proprietary	Proprietary	Proprietary
Wireless frequency	Not applicable	915MHz FCC assigned channel	915MHz FCC assigned channel	915MHz FCC assigned channel	915MHz FCC assigned channel
Power Source	Wall plug for hub (a/c) and batteries in devices	Wall plug for hub (a/c) and batteries in devices	Same	Wall plug for hub (a/c) and batteries in devices	Wall plug for hub (a/c) and batteries in devices
Display	On devices, hub, and monitors connected to Remote Care Management System	On devices, hub, and monitors connected to Remote Care Management System	On devices, hub, and monitors connected to Remote Care Management System	On devices, hub, and monitors connected to Remote Care Management System	On devices, hub, and monitors connected to Remote Care Management System
Video conferencing	Not applicable	Not applicable	Video Conferencing over phone line	Not applicable	2 way Video conference via a broadband internet connection
Medicine Reminders	Not applicable	Not applicable	Not Available	Not applicable	The system reminds the user to take medication if the information is programmed by the Healthcare Provider
Video User Training	Not applicable	Not applicable	Not applicable	Not applicable	Instructional Video clips may be viewed by the user by selecting them from the menu if enabled by the Healthcare Provider

Substantial Equivalence Discussion

The differences between the predicate devices and the BL Healthcare Remote Care Management system are:
The BL Healthcare Remote Care Management system enables videoconferencing and access to the WTVI menu on a specific TV channel.
The BL Healthcare Remote Care Management system provides the ability to videoconference using a broadband connection and for the patient to use the TV screen as a videoconference screen.

The BL Healthcare Remote Care Management system allows the care provider to enable selection of instructional video clips for the patient to view on the TV.
The BL Healthcare Remote Care Management system allows the patient to view uploaded data from the devices and trends.
These differences provide enhanced interaction between the Care provider and the Patient.
The patient is able to videoconference without additional computer systems using the simple TV Interface and a camera.

The BL Healthcare Remote Care Management system uses a secure Broadband Internet connection to transfer data for data transfer similar to the Carematix Wellness System, which uses a phone line or a serial port connection to a computer to send data to an Internet Server.

The BL Healthcare Remote Care Management system connects externally to the FDA approved medical devices using a serial or infrared connection. The devices currently enable the patients to use their devices in this configuration. The differences pose no new risks and the functionality has been demonstrated to be substantially equivalent to the predicate devices.

Non-clinical testing

Similar to the predicate devices, the BL Healthcare Remote Care Management system utilizes devices that have already received 510(k) clearance. The BL Healthcare Remote Care Management system provides and external interface to these FDA approved devices. The external connectivity does not alter the intended use of the devices since the devices provide connectivity to a computer serial port in that configuration.

Substantial equivalence testing demonstrated with objective evidence that the basic functionality of the 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 of the connected devices. The BL Healthcare Remote Care Management system provides and external interface to these FDA approved devices. The external connectivity does not alter the intended use of the devices since the devices provide connectivity to a computer serial port in that configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

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

Re: K051470
Trade Name: Remote Care Management System
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 1, 2005
Received: June 5, 2005

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 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) 276-0295. 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 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/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

K051470

BL Healthcare

Statement of Indication of Use

The **BL Healthcare Remote Care Management system** is for use by patients remotely in combination with a variety of monitoring devices such as blood pressure monitor, blood glucose monitor, and weight scale upon the prescription of a licensed physician or healthcare provider. The BL Healthcare Remote Care Management system serves as the communication link between the compatible devices and the server software at a compatible healthcare facility. The healthcare facility may include healthcare provider, other caregivers, or a disease management center.

The purpose of the 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.

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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K051470