K062338

510(k) SUMMARY

Manufacturer's Name, Contact Person, Address, Phone, Fax, Email, Date Prepared

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OCT 25 2006

Date Prepared: August 2006

Device Name, Common/Generic Name and Classification Name

Proprietary Name: TELEVISIT

Common/Usual Name: Physiological Data Collection System

Classification Name:. Physiological Data Collection System

Predicate Device

Device Name: LifeShirt Real-Time (K043604)
Device Name: March HealthCare Health Monitoring Kit (K060194)

Intended Use of the Device

The TELEVISIT software allows healthcare professionals to conduct remote medical check-ups through interactive sessions with patients who have limited mobility or live in remote locations. The TELEVISIT software is intended for the purposes of collecting physiological data such as: Non-Invasive Blood Pressure; Pulse Oximetry, Temperature and Breath Sounds (Auscultation). The software provides physicians with a tool to schedule appointments with remote patients; to initiate and manage a medical check-up session, to provide data acquisition of medical device data, and to view session reports.

The intended use of the TELEVISIT software is in hospital/clinical environments with established specialized care providing access to each patient in their home and/or local community health center. TELEVISIT software is a non-invasive medical device, which does not flag any abnormal results from the medical device inputs. The TELEVISIT software does not monitor, assess or diagnose a disease, a disorder, or an abnormal physical state. The intended use for the software is data acquisition and collection only, with no treatment function or danger

to the end user. The data obtained from TELEVISIT software can be used only as an aid in the diagnosis and treatment of the patient.

Technological Characteristics

TELEVISIT is consist of the following 3 main components: Televisit Terminal (Patient/Physician), TELEVISIT Medical Device Gateway Box and the TELEVISIT Management Software. FDA Cleared accessories are provided to record physiological data such as: Breath Sounds (Auscultation); Non-Invasive Blood Pressure; Temperature / Thermometry; Pulse Oximetry.

Performance Data

Performance testing included verification and validation that data recorded by the TELEVISIT patient system is accurately transmitted and received by the main computer system and physician's system. Testing confirmed that TELEVISIT meets all of its intended functional requirements.

A risk analysis per ISO 14971: 2000 has been performed to document potential hazards and methods of risk mitigation. The results demonstrate that TELEVISIT is safe and effective.

Substantial Equivalence

TELEVISIT is substantially equivalent to the predicate devices in terms of functional design, indications for use, principles of operation, software platform, and hardware requirements. Televisit software is substantially equivalent to the Lifeshirt Real-Time with Vivo Software (K043604) and March HealthCare Health Monitoring Kit (K060194). Safety and effectiveness of TELEVISIT is comparable to the predicate devices.

TELEVISIT software collects, transmits, archives and produces reports that contain similar information to the predicate devices such as: Process steps include: Scheduling, Session Start, Data Collection, Data Transmission, Data Transfer, Data Record/Store, Data Analyze, Reporting and Archive.

The TELEVISIT system is substantially equivalent in performance and intended use to the predicate devices and does not raise any safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2006

PHD Medical
c/o Ms. Nancy Ruth
Associate Director, Regulatory Services
CanReg Inc.
4 Innovation Drive
Dundas, Ontario L9H 7P3
Canada

Re: K062338
Trade Name: PHD Medical TELEVISIT
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: August 9, 2006
Received: August 10, 2006

Dear Ms. Ruth:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

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

Enclosure

Indications for Use

510(k) Number (if known): K062338

Device Name: TELEVISIT

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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)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062338