HealthCare Vision, Inc.®
Telemedicine Solutions

Section E: 510K Summary

Submitter

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Date Prepared

September 29, 2003

Software Information

Trade Name: Telecare D.R.

Common Name: Telemedicine Communications Module

Classification Name: Powered Communication System

Software Description

The Telecare DR System consists of multiple software and hardware components. Utilizing this system of components, healthcare professionals are empowered with the ability to conduct real-time, secure audio/visual communication and measurement collection encounters from the patient's home to the healthcare facility and presented for secure Internet browser review.

Typically, the Telecare D.R. resides on a health facility's server and connects to the HCV NurseStation. Using the HCV NurseStation software component, the healthcare professional instantiates audio/visual communication with the patient using a standalone videophone system (i.e., CS-126S, CS-126, or CS-146 videophone devices) that is equipped with the capability to transmit and receive data from a variety of external vital

signs and medical measurement devices. The CS 126S also includes an integrated digital stethoscope that provides for both local and remote auscultation functions and an optional accessory plug-in pulse oximetry sensor unit.

Upon connection with a standalone videophone, the HCV NurseStation, located at a healthcare professional's office or facility, identifies all the external vital signs and medical measurement devices (i.e., weight scale, glucometer, vital signs monitor, NIBP, pulse oximetry and spirometer) connected to the standalone videophone. Using the HCV NurseStation, the healthcare professional may proceed to communicate using standard phone line or high speed connection through internal modems and transmit real-time video, audio, and data between them. The real-time video and audio communications allow the patient and caregiver to view and speak with each other.

Using the HCV NurseStation component, the healthcare professional is capable of monitoring the data from the measurement devices in real-time during collection, as well as, storing these measurements to the centralized data repository using the Telecare D.R. server software. To terminate the encounter, the healthcare professional disconnects the video call via the HCV NurseStation software component. This event triggers the HCV Conduit software component, which completes remaining data inserts/updates, broadcasts notifications and prepares data for secure browser viewing via the secure HCV Rendezviewer software component.

With existing legally marketed vital signs measurement devices attached to the patient's system, the health professional and caregiver may monitor the patient's blood pressure, pulse rate, temperature, weight, blood oxygen saturation, blood glucose level, breath peak flow, images, and transmit this data to the caregiver's system. Vital signs measurement devices used with the HCV NurseStation and Telecare D.R. are FDA approved devices and are used for the same purposes which they received 510(k) approval or are devices that are exempt under applicable 21 CFR sections. The data may be captured, displayed, and/or saved on Telecare D.R.

Substantial Equivalence

The Telecare D.R. system and the predicate devices listed above have the same intended use and very similar principles of operations and technological characteristics. The Telecare D.R. and it predicate systems have the same general use to provide the capability for health professionals to monitor remote patient vital signs and/or breath and heart sounds and store the information on a data server/web server over the Internet and over standard phone line. The Telecare D.R. has no internal medical devices and it is a software system that performs as an accessory to 510K medical devices. Communication occurs through a plural of modalities include using standard network connection (H.323), standard phone line (H.324), and wireless communications to connect to devices for recording vital sign data (i.e., blood pressure, pulse, heart rate, oxygen saturation, glucose, weight, ECG, temperature breath peak flow and auscultations of the chest and abdominal cavities). These devices function independently in accordance with their own individual specifications and operation. None of the systems are intended solely for

diagnostic purposes. In general, basic operation for the Telecare D.R. consists of 1) receiving patient vital sign data, images and sounds of the heart, lung, or bowel cavities 2) presenting the data in a graphical and visual format, and 3) providing Internet access to the data by assigned health professionals.

In addition, the following devices can be used with the Telecare D.R. system to provide the external vital signs monitoring functions: Criticare Vital Signs Monitor (K884216) by Criticare Systems Inc., NIBP Monitor UA-767PC (K982481) by A&D Engineering, Inc., Digital Weight Scale UC-321 (exempt under 21 CFR 800.2700) by A&D Engineering, Inc., Ferraris KOKO Peak Pro (K013489) by PDS Healthcare Products Inc., Freestyle Blood Glucose Monitor (K000582) by Therasense. With regards to the transmission of patient vital signs information from external measurement devices, it is equivalent to the Carecompanion Nurse Station/Carecompanion Patient Station (K020584). With respect to the pulse oximetry accessory, it is equivalent to the Zymed Easi-View Telemetry System (K001308).

The main difference from the predicate devices and platforms is that Telecare D.R. is a software component to the predicate devices and systems. Using off-the-shelf hardware and patented technology, Telecare D.R. provides more interface options with approved 510(k) vital sign devices and systems. In addition, the Telecare D.R. uses standard database architecture for managing the vital sign data received from the devices. Telecare D.R. and its predicate devices and systems have the same general use: to provide the capability for health care professionals to monitor blood pressure, pulse, heart rate, oxygen saturation, glucose, weight, ECG, temperature breath peak flow and auscultation sounds of their patients from remote locations. The main functional difference between the systems are the Telecare D.R. is the data server/Web server that permits the storage, retrieval, and presentation of patient-specific vital sign data using standard phone lines and high speed connections over the Internet.

Intended Use

The Telecare D.R. is intended to be used upon prescription of an authorized health care provider by patients to provide two-way audio/video communications, data transmission & communications, transmission of vital signs information over standard telephone lines and high speed telecommunications between the patient, typically at home, and a health professional at the health care professional's site.

The information includes heart, lung, and bowel sounds, blood oxygen saturation, pulse rate, blood pressure, temperature, blood glucose, weight, and breath peak flow measurements. The information is collected upon the request and direction of the health care provider.

The software system is a diagnostic aid that is an accessory to 510(k) devices. Clinical judgment and experience are required to check and interpret the information transmitted. The software system is not intended as a substitute for medical care. The software is

contraindicated for patients requiring direct medical supervision or emergency intervention.

Brief Description of Non-Clinical Testing

Testing was performed to validate the functional performance of the Telecare D.R. Specifically, performance testing of the software was conducted to show that performance exceeds and thus meets the substantial equivalency of the predicate devices. Further testing was performed with each vital signs measurement device to show that they operate equivalently when used with the Telecare D.R. as when operated as independent devices.

Brief Desciption of Clinical Testing

Clinical study information was not submitted for the purpose of demonstrating substantial equivalence to the predicate devices.

Conclusion

The indications for use of the Telecare D.R. software as an accessory of 510(k) devices is consistent with that in labeling for telemedicine communications modules legally marked in the United States.

The results of testing Telecare D.R. with approved 510(k) devices for monitoring or recording vital sign data (i.e., blood pressure, pulse, heart rate, oxygen saturation, glucose, weight, ECG, temperature breath peak flow and auscultations of the chest and abdominal cavities) indicate that the software is substantially equivalent to its predicates and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2004

Mr. Craig Walker
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Re: K033133
Trade Name: Telecare D.R. Server Software System
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (Without Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: January 28, 2004
Received: January 29, 2004

Dear Mr. Walker:

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 (301) 594-4646. 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,

Donna R. Luchner

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

Enclosure

Section D: Indications For Use – Revised 3-30-2004

510(k) Number (if known): K033133

Device Name: Telecare® D.R.

Indications For Use:

The Telecare®D.R. is intended to be used in conjunction with 510(k) certified devices that upon prescription by an authorized healthcare provider for patients provides a means of receiving and storing audio, video, and patient biometric data including vital signs information received over standard phone lines or high speed connection between patients, typically at home, and health professionals at the health care provider's site.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033133