OCT 1 0 2003 K031863

Motion Media Technology Inc.

510K Summary

Submitter

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Date Prepared

June 8, 2003

Device Information

Trade Name: CareStation 126S Videophone

Common Name: Tele Homecare System with Electronic Stethoscope

Classification Name: Radio Frequency Physiological Signal Transmitter and Receiver with Electronic Amplifying Stethoscope

Device Description

The CareStation 126S Videophone system is a standalone videophone system that is equipped with the capability to transmit and receive data from a variety of external vital signs and medical measurement devices. The CareStation 126S also includes an integrated electronic digital stethoscope that provides for both local and remote auscultation functions and an optional accessory plug-in pulse oximetry sensor unit.

Typically, the CareStation is deployed in a patient's home and another CareStation is installed in a healthcare provider or caregiver's office. Each is connected to a standard telephone network connection and the two systems communicate with each other 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 a supplied stethoscope transducer attached to the patient's system, heart, breath, and bowel sounds may be transmitted to the caregiver's system where they may be listened to using a set of stethoscope earphones that are supplied with the system.

With existing legally marketed vital signs measurement devices attached to the patient's system, the caregiver may monitor the patient's blood pressure, pulse rate, temperature, weight, blood oxygen saturation, blood glucose level, breath peak flow, and transmit this data to the caregiver's system. Vital signs measurement devices used with the CareStation system are FDA approved devices and are used for the same purposes for 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 a computer using one or more of a variety of software packages including CareStation for Windows™. The CareStation may be configured for use with one to three external devices

Substantial Equivalence

As a multifunction device, the CareStation system is substantially equivalent to the following predicate systems: With respect to the transmission of patient vital signs information from external measurement devices, it is equivalent to the CareCompanion Nurse Station / Care Companion Patient Station (#K020584). With respect to the integrated electronic stethoscope, it is equivalent to the CareTone II Telephonic Stethoscope (#K963678). With respect to the pulse oximetry accessory, it is equivalent to the Zymed Easi-View Telemetry System (#K001308).

In addition, the following devices can be used with the CareStation 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.

The CareStaton and its predicate systems have the same general use: to provide the capability for health care professionals to monitor the vital signs and/or heart and breath sounds of their patients from remote locations.

The main functional difference between the systems are the CareStation extends the capabilities of remote auscultation by providing a real-time video and audio link along with the heart, breath, and bowel sounds.

Intended Use

The CareStation 126S is intended to be used upon prescription of an authorized healthcare provider by patients to provide two-way video, audio, and data communications including patient vital signs information over standard telephone lines between the patient, typically at home, and a health care professional at the health care provider'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 device does not send any real-time alarms. The device is a diagnostic aid. Clinical judgment and experience are required to check and interpret the information transmitted. The device is not intended as a substitute for medical care. The device 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 CareStation. In particular, specific performance testing of the integrated digital stethoscope functions was performed to show that the performance exceeds and thus meets substantial equivalency of the predicate device. Further, testing was performed with each vital signs measurement device to show that they operate equivalently when used with the CareStation as when operated as independent devices.

The CareStation has been subjected to performance testing to applicable safety, mechanical, electrical, electromagnetic compatibility (EMC), and environmental standards. Such specifications for the reference appropriate international standards. All specifications were met.

Brief Description of Clinical Testing

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

Conclusion

The indications for use of the digital stethoscope feature of the CareStation system is consistent with that in labeling for electronic stethoscopes legally marked in the United States as well as that in the FDA classification regulation under 21 CFR 870.1875(b) for this generic type of device.

The indications for use of the accessory pulse oximeter sensor with the CareStation system is consistent with that in labeling for pulse oximeters legally marketed in the United States as well as that in the FDA classification regulation under 21 CFR 870.2700 (b) for this generic type of device.

The results of testing the CareStation with the integrated electronic stethoscope, pulse oximeter, and other vital signs measurement devices indicate that the device is substantially equivalent to it's predicate devices 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

OCT 1 0 2003

Motion Media Technology Inc.
c/o Mr. Stuart R. Ross
Chief Technology Officer
Motion Media Technology Inc.
6714 Netherlands Drive
Wilmington, NC 28405

Re: K031863
Trade Name: CareStation 126S
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: September 12, 2003
Received: September 22, 2003

Dear Mr. Ross:

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,

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

Applicant: Motion Media Technology Inc.

510(k) Number (if known):

Device Name: CareStation 126S

Indications For Use:

The CareStation CS126S is intended to be used upon prescription of an authorized healthcare provider by patients to provide two-way video, audio, and data communications including patient vital signs information over standard telephone lines between the patient, typically at home, and a health care professional at the health care provider'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 device does not send any real-time alarms. The device is a diagnostic aid. Clinical judgment and experience are required to check and interpret the information transmitted. The device is not intended as a substitute for medical care. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031863

Prescription Use ✓ OR Over-the-counter Use ____
(Per 21 CFR 801.109)