K022274
page 1 of 3

neptec

MAY 2 9 2003

ISO 9001 Registered

510(k) Summary

Submitter

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Contacts

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Date Prepared

July 5, 2002

Device Information

Trade Name:	CareCompanion Nurse Station / CareCompanion Patient Station
Common Name:	Tele Homecare System
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver

Device Description

The CareCompanion System consists of two components: a transportable Patient Station installed typically in a patient's home; and the Nurse Station, installed in a healthcare provider or professional caregiver's office. The two components communicate with each other through modems over standard telephone lines and transmit real-time video, audio and data between them.

The real-time video and audio communications allow the patient and the caregiver to view and speak with each other.

Using vital signs measurement devices integrated with the Patient Station, the Patient Station is designed to monitor the patient's blood pressure, pulse rate, blood glucose level, weight, blood oxygen saturation level and/or heart, lung and bowel sounds, and transmit this data to the Nurse Station. The data is displayed to the caregiver operating the Nurse Station and also automatically recorded in a patient information database. The heart, lung and bowel sounds may be listened to by the caregiver using a set of headphones supplied with the system.

The Nurse Station consists of two sub-components, the Nurse Station PC, which is a standard PC with supporting peripherals connected to a videophone, which provides the video conferencing functions for the Nurse Station. The Nurse Station PC may also operate as a standalone device for patient data management and record keeping functions.

Substantial Equivalence

The Neptec CareCompanion with the addition of the pulse oximeter is substantially equivalent to the predicate Neptec CareCompanion (#K020584) that has previously been approved by the FDA.

The CareCompanion and its predicate have the same general use to provide the capability for health care professionals to monitor the vitals signs of their patients from remote locations.

The main difference between the systems is the addition of a pulse oximeter for the collection of blood oxygen saturation data.

The pulse oximeter is substantially equivalent to the following FDA approved devices:

- Nonin Palmsat Pulse Oximeter Model 2500 (#K002690) by Nonin Medical, Inc.
- 9303 Neonatal/Adult Vital Signs Monitor (#K982776) by CAS Medical Systems, Inc.
- Escort II Modular Telemetry System (#K970763) by Medical Data Electronics, Inc.
- DR180-R/Oxy Holter and Pulse Oximetry Recorder (#K983576) by Northeast Monitoring, Inc.
- Digital EEG and Sleep Acquisition System (#K990522) by La Mont Medical, Inc.

Intended Use

The Patient Station is intended to be used upon prescription of an authorized healthcare provider by patients as a means to collect and transmit 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: blood pressure, pulse rate, blood glucose level, weight, blood oxygen saturation level and

heart, lung and bowel sounds. The information is collected upon request and direction of the healthcare provider.

The CareCompanion Patient Station is intended to be used in conjunction with the CareCompanion Nurse Station to provide two-way video, audio and data communications between the patient and the health care professional.

The device does not send any real-time alarms. The device is a diagnostic aid. Clinical judgement 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.

Performance Testing

Testing was performed to validate the functional performance of the CareCompanion. In particular, testing was performed with each vital signs measurement device to show that they operate equivalently when integrated with CareCompanion as when operated as independent devices. The pulse oximeter was tested to verify comformance with manufacturer's specifications.

In addition, the CareCompanion Patient Station and the CareCompanion Nurse Station have been subjected to performance testing to applicable mechanical, electrical and environmental standards.

Conclusion

The results of the test indicate that the device is substantially equivalent to its predicate device 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

MAY 2 9 2003

Neptec Design Group, Ltd.
c/o Mr. John Schneider
HINS Project Manager
302 Legget Drive
Kanata, Ontario
Canada K2K 1Y5

Re: K022274
Trade Name: Carecompanion patient station & nurse station
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: March 6, 2003
Received: March 10, 2003

Dear Mr. Schneider:

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 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,

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

Enclosure

K022274

510(k) Number (if known):

Device Name: CareCompanion Nurse Station / CareCompanion Patient Station

Indications For Use:

The CareCompanion Patient Station is intended to be used in conjunction with the CareCompanion Nurse Station to provide two-way video, audio and data communications between the patient and the health care professional.

The CareCompanion Patient Station is used upon prescription of an authorized healthcare provider by patients where regular monitoring of vital signs information is indicated. The information is collected from the CareCompanion Patient Station and transmitted over standard telephone lines to a health care professional.

The device does not send any real-time alarms. The device a aid. Clinical judgement 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K022274