NOV 1 4 2001

K012801

510(k) Summary

Submitter

Neptec Design Group Ltd.
302 Legget Drive
Kanata, Ontario Canada
K2K 1Y5

Contacts

John Schneider
Neptec Design Group Ltd.
Tel: 613-599-7602
Fax: 613-599-7604

or

Charles H. Kyper
Kyper & Associates
Chapel Hill, NC
Tel: 919-960-0049
Fax: 919-960-0009

Date Prepared

August 20, 2001

Device Information

Trade Name: N2000 Base Station / N2001 Nurse Station

Common Name: Tele Homecare System

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Device Description

The HomeCare Information Network System (HINS) consists of two components: a transportable N2000 Base Station installed typically in a patient's home; and the N2001 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.

With existing legally marketed vital signs measurement devices integrated with the N2000 Base Station, the N2000 Base Station is designed to monitor the patient's blood pressure, pulse rate, blood oxygen saturation, blood glucose level, temperature, weight and/or heart, lung and bowel sounds, and transmit this data to the N2001 Nurse Station. The data is displayed to the caregiver operating the N2001 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.

Vital signs measurement devices integrated in the HINS are FDA approved devices and are used for the same purposes for which they received 510(k) approval. The N2000 may be configured for use with one to five devices.

The N2001 Nurse Station consists of two sub-components, the N2001 Nurse Station PC, which is a standard PC with supporting peripherals connected to the N2000 Base Station, which provides the video conferencing functions for the Nurse Station. The N2001 Nurse Station PC may also operate as a standalone device for patient data management and record keeping functions.

Substantial Equivalence

The Neptec Homecare Information Network System (HINS) is substantially equivalent to to following predicate systems: the Electronic HouseCall System (#K000237) by Cybercare, Inc., and the Aviva Systems (#K981533) by American Telecare, Inc. In addition, the Digital Blood Pressure Monitor (#K982481) by A & D Engineering, Inc. and the Stethos™ Electronic Stethoscope (#K001306) by Andromed, Inc. may be used with the system to provide the vital signs monitoring functions.

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

The main functional differences between the systems are that the predicate devices provide the capability to generate higher resolution images allowing heath care professionals to perform a range of assessment functions including wound care. This feature is not an indicated use for the HINS. The Electronic HouseCall System by Cybercare is also capable of communicating over ISDN, DSL or Internet links in addition to standard telephone lines. These differences, however, are not significant with regard to performance or safety of the vital signs data monitoring and collection functions.

Intended Use

The N2000 Base 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 oxygen saturation, blood glucose level, temperature, weight, and heart, lung and bowel sounds. The information is collected upon request and direction of the healthcare provider.

The N2000 Base Station is intended to be used in conjunction with the N2001 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 not intended to be used for diagnostic purposes. 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

The N2000 Base Station and the N2001 Nurse Station have been subjected to performance testing of vital signs measurements, performance to specifications, and electromagnetic environmental susceptibility and emissions in compliance with:

• IEC 601-1	Medical Electrical Equipment
• CAN/CSA-C22.2	Medical Electrical Equipment
• UL 2601-1	Safety of Medical Electrical Equipment
• FCC Part 15, Subpart C	FCC Rules and Regulations

Testing was performed to validate the functional performance of the HINS. In particular, testing was performed with each vital signs measurement device to show that they operate equivalently when integrated with HINS as when operated as independent devices.

Conclusion

The results of the test 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

NOV 14 2001

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

Re: K012801
Trade Name: N2000 Base Station and N2001 Nurse Station HomeCare Information Network System
Regulation Number: 21 CFR 870. 1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 20, 2001
Received: August 21, 2001

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.

1

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 4 2001

510(k) Number (if known): K012801

K012801

Device Name: N2000 Base Station / N2001 Nurse Station

Indications For Use:

The N2000 Base Station is intended to be used in conjunction with the N2001 Nurse Station to provide two-way video, audio and data communications between the patient and the health care professional.

The N2000 Base 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 N2000 Base Station and transmitted over standard telephone lines to a health care professional.

The device does not send any real-time alarms. The device is not indicated for diagnostic purposes. 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)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012801