K041308

JUN 2 8 2004

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: WEBVMC, LLC
2-Address: 904 Center Street. Conyers, GA 30012 USA
3-Phone: (770) 602-3189
4-Fax: (678) 413-2033
5-Contact Person: Scott Sheppard, President
6-Date summary prepared: April 5th, 2004
7-Device Trade or Proprietary Name: RemoteNurse™ Patient Monitoring system
8-Device Common or usual name: Remote Patient Monitoring System
9-Device Classification Name: Remote Patient Monitoring System
10-Substantial Equivalency is claimed against the following devices:

1- K030222 by American Telecare, Inc
2- K022274 by Neptec Design Group Ltd

11-Description of the Device:

The device "RemoteNurse™ Patient Monitoring system" is a monitoring tool prescribed by a licensed physician when time-critical care is not required, for the purpose of providing caregivers remote access to vital sign measurements of patients at home, as captured on commercially available medical devices designed for home use, and transmitted to a database retrieved from a secure website. It is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data.

The device is contraindicated for patients with uncompensated heart failure, patients at high risk of life threatening arrhythmias, patients with recent myocardial infarctions, or patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable to self-administrate it.

Clinical judgment and experience are required to check and interpret the information delivered.

The RemoteNurse™ Patient Monitoring system consists of:

(1) RemoteNurse™ Patient Station –which is a computer with a touch sensitive screen- for capturing patient's vital signs from devices manufactured by others. The RemoteNurse™ Patient Station provides a user interface for displaying reminder information as well as prompting for patient responses to pre-defined questions.

(2) RemoteNurse™ software application for capturing, storing and forwarding patient's vital signs to a secure website via either a standard telephone lines or LAN/WAN.

(3) RemoteAccess™ software application to allow caregiver to review patient's vital signs on the secure website. RemoteAccess™ software application allows for pre-defining limits above or below which it emails and/or pages the caregiver.

(4) Processor software application to manage the interface between RemoteNurse™ software application and the website.

Typical devices that may be connected to RemoteNurse™ Patient Station are:

Blood Pressure Monitor, Glucose Meter, Weight Scale, Pulse-oxidation, Peak Flow, ECG and PT/INR.

Also, digital camera may be connected to RemoteNurse™ Patient Station.

The unit supports up to 8 devices in the same time.

PAGE E1 REVISED

K041308

12-Intended use of the device:

The device "RemoteNurse™ Patient Monitoring system" is a monitoring tool prescribed by a licensed physician when time-critical care is not required, and is intended for use to provide caregivers remote access to vital sign measurements of patients at home, as captured on commercially available medical devices designed for home use, and transmitted to a database retrieved from a secure website. It is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data.

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Also, digital camera may be connected to RemoteNurse™ Patient Station.
The unit supports up to 8 devices in the same time.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SIMILAR** to the predicate device.

REFER TO MAIN SUBMISSION FOR COMPLETE DETAILS

FDA file reference number	510k # K022274 & K030222
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Similar
Target population	Similar
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Not applicable
Biocompatibility	Not applicable
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Not applicable
Radiation safety	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2004

WEBVMC, LLC
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K041308
Trade Name: WEBVMC RemoteNurse™ Patient Monitoring System
Regulation Number: 21 CFR 870.2920
Regulation Name: Electrocardiograph telephone transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 11, 2004
Received: June 15, 2004

Dear Mr. Job:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K041308

Device Name: WEBVMC RemoteNurse™ Patient Monitoring system

Indications For Use:

The device "RemoteNurse™ Patient Monitoring system" is a monitoring tool prescribed by a licensed physician when time-critical care is not required, and is indicated for use to provide caregivers remote access to vital sign measurements of patients at home, as captured on commercially available medical devices designed for home use, and transmitted to a database retrieved from a secure website. It is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data.
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The unit supports up to 8 devices in the same time.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041308

PAGE E3