AUG 19 2003

K030222

1/2

510(k) SUMMARY

American TeleCare's

NX System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

American TeleCare, Inc.
7640 Golden Triangle Drive
Eden Prairie, MN 55344-3732

Contact Person:

Pete Plucinak
American TeleCare, Inc.
Telephone: (952) 897-0000
Facsimile: (952) 941-2247

Date Prepared: August 15, 2003

Name of Device

NX System

Common or Usual Name

Telemedicine Communications Module

Classification Name

Powered Communication System

Predicate Devices

American TeleCare's Aviva 200 System

Indications for Use:

The NX System is intended to be used as a monitoring device when time-critical care is not required. The peripheral devices compatible with the NX System are blood pressure, pulse, weight, oxygen saturation, glucose and PT/INR. The NX System enables the home –bound patient to retrieve data taken by the peripheral devices and forward them to an off-site central location for access by a health care professional.

Substantial Equivalence

The NX System and the predicate device (Aviva 200 System) listed above have the same intended use and very similar principles of operation and technological characteristics. These systems are intended for use as monitoring devices, whereby results from medical devices can be obtained by the NX System and forwarded to the Data Server/Web Server over the Internet.

The NX System has no internal medical devices. Communicating through its standard interface ports using radio waves, the NX System can wirelessly connect to devices for measuring blood pressure, pulse, weight, oxygen saturation, glucose and PT/INR. These devices function independently in accordance with their own individual specifications and operation. None of the systems are intended to be used for diagnostic purposes.

In general, basic operation for both systems consists of: (1) obtaining readings for medical device peripherals and (2) forwarding those data to the system's Server.

The only difference from the predicate Aviva 200 System is that the NX System uses a custom PC platform for its patient station (NX Monitoring Station) instead of an off-the-shelf PC and the NX System has more interface options to stand-alone medical device peripherals. Further, the NX system uses wireless technology to connect to the stand-alone medical devices.

These minor variations to the predicate devices do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2003

American TeleCare, Inc.
c/o Mr. Charles R. Abbruscato
Chief Technology Officer
7640 Golden Triangle Drive
Eden Prairie, Minnesota 55344

Re: K030222
Trade Name: NX System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: May 19, 2003
Received: May 21, 2003

Dear Mr. Abbruscato:

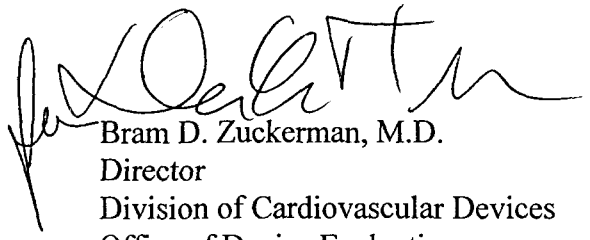
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

510(k) Number (if known): KO30222

Device Name: NX System

Indications for Use:

The NX System is intended to be used as a monitoring device when time-critical care is not required. The peripheral devices compatible with the NX System are blood pressure, pulse, weight, oxygen saturation, glucose and PT/INR. The NX System enables the home–bound patient to retrieve data taken by the peripheral devices and forward them to an off-site central location for access by a health care professional.

(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 KO30222

Prescription Use: X OR Over-the-Counter Use _____
(Per CRF 801.109)

(Optional Format 1-2-96)