K003999/S1

JUN 2 8 2001

510(k) SUMMARY

American TeleCare's

Aviva 200 Systems

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:

Charles Richard Abbruscato
American TeleCare, Inc.
Telephone: (612) 897-0000
Facsimile: (612) 941-2247

Date Prepared: December 15, 2000

Name of Device

Aviva 200 System

Common or Usual Name

Telemedicine Communications Module

Classification Name

Powered Communication System

Predicate Devices

(1) American TeleCare's Aviva Systems
(2) American TeleCare's Aviva SLX System

Substantial Equivalence

The Aviva 200 System and the predicate devices (Aviva SLX and Aviva Systems) listed above have the same intended use and very similar principles of operation and technological characteristics. Specifically, all systems include a video/audio communications capability and medical devices. These systems are intended for use as monitoring devices, whereby a health care professional can, from a remote location, communicate with the patient to gather blood pressure and pulse readings and glucose readings. The Aviva 200 System can also send the readings to the Data Server without the nurse's involvement. None of the systems ares intended to be used for diagnostic purposes.

In general, basic operation for all systems consists of: (1) establishing voice/video communication and (2) obtaining blood pressure and pulse readings during a video visit.

The only difference from the predicate Aviva SLX and Aviva Systems is that the Aviva 200 System has the capability to 1) transfer blood pressure and pulse readings to a Data Server separate from a video visit.

The Aviva 200 Systems use the same blood pressure meter and the same glucose meter as the predicate devices. These minor modifications 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

JUN 2 8 2001

Mr. Charles Richard Abbruscato
American Telecare, Inc.
7640 Golden Triangle Drive
Eden Prairie, MN 55344

Re: K003999
Trade Name: Aviva 200 System
Regulation Number: 870.2300
Regulatory Class: II (two)
Product Code: MWI, DRG and DXN
Dated: April 2, 2001
Received: April 4, 2001

Dear Mr. Abbruscato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

510(k) Number (if known): K003999

Device Name: Aviva 200 System

Indications For Use:

The Aviva 200 System is intended to be used as a monitoring device, whereby a health care professional, from a remote location, can communicate with the patient and gather blood pressure, pulse and glucose readings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003999

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)