K993550

JAN 1 3 2000

510(k) SUMMARY

American TeleCare's

Aviva SLX 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:

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

Date Prepared: October 19, 1999

Name of Device

Aviva SLX Systems

Common or Usual Name

Telemedicine Communications Module

Classification Name

Powered Communication System

Predicate Devices

(1) American TeleCare's Personal Telemedicine Module
(2) American TeleCare's Digital Personal Telemedicine Module
(3) American TeleCare's Personal Telemedicine System

Substantial Equivalence

The Aviva SLX System and the predicate device (Aviva System) listed above have the same intended use and very similar principles of operation and technological characteristics. Specifically, both devices consist primarily of a blood pressure meter, a telephonic stethoscope, and a communications circuit. These devices are intended for use as monitoring devices, whereby a health care professional can, from a remote location, communicate with the patient between visits to gather blood pressure and pulse readings, as well as to listen to the patient's heart and lung sounds. Neither device is intended to be used for diagnostic purposes.

In general, basic operation of the devices consists of: (1) establishing voice/video communication; (2) establishing communication between the sending and receiving units of a telephonic stethoscope to obtain heart and lung sounds; and (3) obtaining blood pressure and pulse readings.

The only difference from the predicate Aviva System is that the Aviva SLX System has the capability to 1) transmit the blood pressure/pulse readings from the Patient Station to the Central Station and clear the readings from the blood pressure/pulse meter; and 2) obtain glucose readings from an off-the-shelf glucose meter plugged into the data port of the Patient Station and transmit those readings to the Central Station, as well as to clear the readings from the glucose meter. The Aviva SLX Systems use the same blood pressure meter and the same telephonic stethoscope as the predicate device. 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

JAN 13 2000

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

Re: K993550
Aviva SLX System Model SL1010
Regulatory Class: II (two)
Product Code: DRG
Dated: October 19, 1999
Received: October 20, 1999

Dear Mr. Abbruscato:

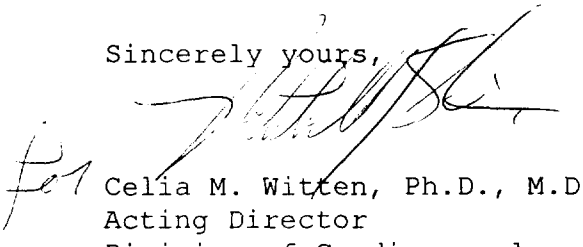
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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"(21 CFR 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 Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K993550

Device Name: Aviva SLX System

Indications For Use:

The Aviva SLX System is intended for use as a monitoring device, whereby a health care professional can, from a remote location, communicate with the patient between visits to gather blood pressure, pulse and glucose readings, as well as to listen to the patient's heart and lung sounds.

(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, Respiratory,
and Neurological Devices
510(k) Number K993550

(Optional Format 3-10-98)