

JUL 15 1998

X981533

**510(k) SUMMARY**

**American TeleCare's**

**Aviva 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: April 28, 1998

**Name of Device**

Aviva 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 Systems and the predicate devices listed above have the same intended use and very similar principles of operation and technological characteristics. Specifically, all three 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. None of the devices are intended to be used for diagnostic purposes.

In general, operation of the devices consists of: (1) establishing voice/video communication; (2) establishing communication between the sending and receiving units of a telephonic stethoscope; (3) obtaining and conveying a blood pressure and pulse reading; and (4) obtaining and transmitting heart or lung sounds.

The only difference from the Personal Telemedicine System is that the Aviva Systems contain a standards based (H.324) video phone instead of an older proprietary video phone. The difference from the PTM and Digital PTM is that the Aviva Systems include a video phone to be used with the PTM and Digital PTM. The Aviva Systems use the same blood pressure meter and the same telephonic stethoscopes as the predicate devices. These minor modifications to the predicate devices do not raise new questions of safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 15 1998

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

Re: K981533  
American TeleCare, Inc. Aviva Systems  
Regulatory Class: II (two)  
Product Code: DRG  
Dated: April 28, 1998  
Received: April 29, 1998

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 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K981533

Device Name: Aviva Systems

**Indications For Use:**

The P1M Systems are 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 and pulse 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)**

*[Handwritten Signature]*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K981533

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use