

K 9641554

**510(k) Summary**

**American Telecare, Inc.'s**

**Personal Telemedicine Module**

**Submitter's Name, Address, and Telephone Number**

American Telecare, Inc.  
7680 Golden Triangle Drive  
Eden Prairie, MN 55344-3732  
Telephone: (612) 897-0000  
Facsimile: (612) 944-2247

**Contact Persons**

C. Richard Abbruscato  
American Telecare, Inc.  
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Eden Prairie, MN 55344-2247  
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or

Gerard J. Prud'homme, Esq.  
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Telephone: (202) 637-5735  
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(as Regulatory Counsel to American  
Telecare, Inc.)

**Date Prepared**

November 8, 1996

**Name of Device**

Personal Telemedicine Module

**Classification Name**

Powered Communication System

**Common Name**

Telemedicine Communications Module

**Product Code**

ILC

**Predicate Device**

American Telecare Inc.'s Personal Telemedicine System (K952882)

**Intended Use**

American Telecare, Inc.'s Personal Telemedicine Module ("PTM 1") is intended to be used solely as a monitoring device, whereby a health care professional can communicate with the patient

between visits to gather blood pressure and pulse readings, and to listen to the patient's heart and lung sounds.

### **Substantial Equivalence**

The PTM 1 is used by the patient in conjunction with a videophone, PC-based video conferencing system or other means for the health care professional to talk with the patient or attending nurse. The patient or attending nurse uses the PTM 1's blood measure meter and display to take the patient's blood pressure and pulse rate. The patient or attending nurse reads the blood pressure and pulse values from the display and repeats them into the PTM 1's microphone for the health care professional to hear at his/her end. The patient or attending nurse places the chest piece on the appropriate body region to pick up either heart, lung, or bowel sounds. The sounds are transmitted to the health care professional who has the receiving end unit of American Telecare's cleared CareTone I telephonic stethoscope. The health care professional advises the patient or attending nurse as to the placement of the chest piece over the communications line ending at the PTM 1's speaker. The PTM 1 operates with many off-the shelf desk top PC-based video conferencing systems ("video system") through the video system's audio interface.

The PTM 1 consists of a blood pressure meter, a telephonic stethoscope and a speaker/microphone circuit. Both the blood pressure meter and telephonic stethoscope have been cleared by FDA. Neither device has been altered for use with the PTM 1. Instead, they have been placed in a common enclosure for the convenience of the patient. The principal differences between the PTM 1 and the PTS are: (1) the removal of the videophone; (2) the addition of the speaker/microphone circuitry; and (3) the modification of the enclosure.

The removal of the videophone does not raise new issues of safety or effectiveness because: (1) there is no change in the method of transmitting the blood pressure, pulse or stethoscope sounds from the patient to the physician; and (2) the modification is made merely to permit use with any other compatible PC-based video conferencing system. The use of the speaker/microphone circuitry also does not raise new issues of safety or effectiveness because the circuitry uses technology very similar to the speaker phone on the PTS which is well understood. Finally, the minor difference in enclosure dimensions also does not raise any new issues of safety or effectiveness because the Company has conducted testing which demonstrates the compatibility of this device in the new enclosure.



DEC 17 1996

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. C. Richard Abbruscato  
American TeleCare, Inc.  
7680 Golden Triangle Drive  
Eden Prairie, Minnesota 55344-3732

Re: K964554  
Personal Telemedicine Module  
Regulatory Class: II (two)  
Product Code: 74 DRG  
Dated: September 12, 1996  
Received: September 13, 1996

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.

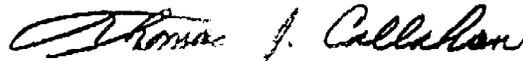
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4659. 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 at (301) 443-6597.

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): \_\_\_\_\_

Device Name: Personal Telemedicine Module

**Indications For Use:**

The Personal Telemedicine Module is intended to be used solely as a monitoring device, whereby a health care professional can communicate with the patient between visits to gather blood pressure and pulse readings, and 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)

*Richard Blalock*

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

510(k) Number     K964554    

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_