

**510K SUMMARY**

**American TeleCare's Digital  
Personal Telemedicine Module**

DEC 29 1997

**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.  
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Date Prepared: October 9, 1997

**Name of Device**

Digital Personal Telemedicine Module

**Common or Usual Name**

Telemedicine Communications Module

**Classification Name**

Powered Communication System

**Predicate Devices**

1. American TeleCare's Personal Telemedicine Module (K964554); and
2. American TeleCare's CareTone II Telephonic Stethoscope (K963678)

## **Substantial Equivalence**

The Digital Telemedicine Module ("Digital PTM") and the predicate devices listed above have the same intended use and principles of operation and very similar technological characteristics. Specifically, both the Digital PTM and the Personal Telemedicine Module ("PTM") consist primarily of a blood pressure meter, a telephonic stethoscope, and a speaker/microphone circuit; these three components are placed in a common housing but are not interconnected by hardware or software. Both 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, operation of either device consists of: 1) connecting the device to a video system; 2) establishing voice/video communication; 3) establishing communication between the sending and receiving units of a telephonic stethoscope; 4) obtaining a blood pressure and pulse reading; and 5) obtaining and transmitting to heart or lung sounds.

The only difference between the two devices is that the PTM contains American TeleCare's CareTone Telephonic Stethoscope ("CareTone"), while the Digital PTM contains American TeleCare's CareTone II/LBR Telephonic Stethoscope ("CareTone II/LBR"), the second generation model of American TeleCare's CareTone II Telephonic Stethoscope ("CareTone II"). This minor modification to the technological characteristics of the Digital PTM does not raise new questions of safety or effectiveness, because 1) the Digital PTM is a kit that provides the telephonic stethoscope in a common enclosure with the blood pressure monitor and the microphone/speaker circuit for the convenience of the patient; 2) the telephonic stethoscope is not interconnected with the other components of the Digital PTM; and 3.) the modifications made to the CareTone II/LBR, when compared with the CareTone II's characteristics, do not raise new questions or effectiveness regarding the stethoscope. Thus, the Digital PTM is substantially equivalent to the predicate devices.

With regard to the telephonic stethoscopes, the primary differences between the CareTone II and the CareTone II/LBR are: 1) the method used to encode the auscultatory sounds from the analog signal to a digital binary signal; 2) the process by which data are received at the receiving end unit of the telephonic stethoscope. These technological differences do not raise new questions of safety or effectiveness; bench testing and clinical studies demonstrate that these modifications do not adversely affect the quality of the transmitted signal.

Thus, the CareTone II/LBR is substantially equivalent to the CareTone II; therefore, as described above, the Digital PTM is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

DEC 29 1997

Mr. C. Richard Abbruscato  
Vice President, Engineering and Manufacturing Operations  
American TeleCare, Inc.  
7640 Golden Triangle Drive  
Eden Prairie, MN 55344

Re: K973873  
Trade Name: Digital Personal Telemedicine Module  
Regulatory Class: II (two)  
Product Code: 74 DRG  
Dated: October 9, 1997  
Received: October 10, 1997

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 (Pre-market 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.

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): K973873

Device Name: Digital Personal Telemedicine Module

Indications For Use:

The Digital 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, 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)

*[Signature]*  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K973873

Prescription Use   
(21 CFR 801.109)

OR

*[Signature]*  
Over-The-Counter Use