

K952882

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**510(k) Summary of  
Safety and Effectiveness**

Submitter: American TeleCare, Inc. Date of Summary: 6/22/95  
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Product: Classification Name: Powered Communications Product (21 CFR 890.3710)  
Generic Name: Telemedicine Communication Product  
Trade/Proprietary Name: Personal Telemedicine System

**Substantially Equivalent Products:**

Digital Blood Pressure Monitor as manufactured by A & D Medical  
TelePhonic Stethoscope as manufactured by American TeleCare, Inc.  
Image Management System and Corabi DX2000 Dynamic Module as manufactured by  
Corabi International Telemetrics, Inc. and Apollo Software, Inc.

Description: The Personal Telemedicine System (PTS) is an assembly of medical products, each of which was previously cleared by the FDA for commercial distribution to patients for their in home use. These products are assembled into a housing which incorporates a videophone and speakerphone and thereby allows a medical practitioner to communicate directly with a patient in a remote location, both verbally and visually, to perform an examination.

Use of the PTS begins by either the medical practitioner placing a call to the patient's videophone or the patient pushing the "CALL" button on the PTS unit to notify the medical practitioner to call them. The medical practitioner then determines the patient's status through questions and answers, through visual examination via the videophone, and through use of the medical products. Visual examination is enhanced by the patient placing themselves in relation to the camera portion of the videophone and by use of a specially made magnifying lens placed in front of the camera portion of the videophone. The medical practitioner walks the patient through use of the medical products and the results of each test are presented verbally to the medical practitioner.

The medical products in the PTS unit are being used for the same purposes for which they received 510(k) clearance. The unit as a whole, however, has never been submitted to the FDA for clearance.

Intended Use: The American TeleCare, Inc. Personal Telemedicine System (PTS) is intended to be used to transmit medical information between a patient at one location, typically in their home, and a medical practitioner at another location, typically a home care

nurse at a central nursing station. Information is transmitted over normal residential telephone lines and utilizes two-way video and voice communication.

The PTS is typically used in home health care situations as an augment to home care nursing.

In essence, the PTS allows a medical practitioner to make a "video-visit"™ to the patient rather than a physical visit. In this "video-visit," the medical practitioner can conduct many of the same diagnostic tests that would be performed in a physical visit.

#### Comparison to Substantially Equivalent Products:

The American TeleCare, Inc. Personal Telemedicine System (PTS) is equivalent to the medical equipment from which it is assembled, with the addition of the telecommunications equipment. This additional equipment is equivalent to the Corabi/Apollo equipment in that it conveys the medical information gathered at a remote site to a central location for diagnostic evaluation. Both use specialized hardware to accomplish this task, and convey the information using standard household energy sources and telephone equipment.

The Corabi/Apollo equipment uses a personal computer while the PTS does not. The PTS uses several pieces of home use medical equipment while the Corabi/Apollo does not. The PTS conveys some auditory as well as visual information while the Corabi/Apollo conveys only visual information.