

FEB - 1 2005

K043368

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## Attachment 4

**510(k) Summary  
As Required by 807.92  
For ViTelCare™ Turtle 400 Patient Monitoring System  
Prepared on November 22<sup>nd</sup>, 2004**

Submitted By: ViTel Net  
8201 Greensboro Drive, Suite 600  
McLean, VA 22102

Tel. (703) 448-0999 Fax: (703) 749-9559

Contact Person: Allen Izadpanah  
President and Chief Executive Officer

Device Trade Name: ViTelCare™ Turtle 400 Patient Monitoring System

Common Name: Turtle 400 Patient Monitoring System

Classification: Not Classified

Predictive Device: ViTelCare™ Patient Monitoring System (K040581)

Manufactured By: ViTel Net  
221 Elizabeth Street  
Utica, NY 13501

Description of The Device: The ViTelCare™ Turtle 400 Patient Monitoring System is a PC based Telemedicine system adapted to the collection, management, and communication of patient monitoring data from home and group care environments.

Intended Use For This Device: Indications for Use: ViTelCare™ Turtle 400 Patient Monitoring System is intended to be a communication tool for an in-home patient that acquires, accumulates, and transmits vital signs information, self-assessment of physical condition, and other physiological data to a healthcare practitioner located remotely from the patient. The patient information is received and stored on the MedVizer™ ViTelCare Call Center where a qualified healthcare practitioner can review the patient information and data. The communication connectivity between patient and healthcare practitioner is via a standard public telecommunications utility to the Internet. Decisions concerning

diagnosis and treatment are to be performed by qualified healthcare professionals.

Substantial Equivalence to Predicate Device: The ViTelCare™ Turtle 400 Patient Monitoring System is virtually identical to the ViTelCare™ Patient Monitoring System. There are no technical differences with any implications for safety and effectiveness. The labeling of ViTelCare™ Turtle 400 Patient Monitoring System includes extensive protocols for monitoring patients with medical conditions. These have been derived from guidelines published by the VA, DoD, and other national organizations.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 1 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Visual Telecommunications Network  
c/o Mr. Allen Izadpanah  
8201 Greensboro Drive  
Suite 600  
McLean VA 22102

Re: K043368

Trade Name: VitelCare™ Turtle Patient Monitoring System

Regulation Number: 21 CFR 870.2300

Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)

Regulatory Class: II (two)

Product Code: MWI

Dated: January 11, 2005

Received: January 12, 2005

Dear Mr. Izadpanah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Brian D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043368

Device Name: ViTelCare™ Turtle 400 Patient Monitoring System

Indications for Use: ViTelCare™ Turtle 400 Patient Monitoring System is intended to be a communication tool for an in-home patient that acquires, accumulates, and transmits vital signs information, self-assessment of physical condition, and other physiological data to a healthcare practitioner located remotely from the patient. The patient information is received and stored on the MedVizer™ ViTelCare Call Center where a qualified healthcare practitioner can review the patient information and data. The communication connectivity between patient and healthcare practitioner is via a standard public telecommunications utility to the Internet. Decisions concerning diagnosis and treatment are to be performed by qualified healthcare professionals.

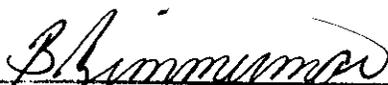
Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K043368