K050128
p1/2

MAY 13 2005

E 510 (K) Summary

Submitter's Name:	TeleVital Inc.
Submitter's Address:	1326 Piper Drive, Milpitas CA
Submitter's Telephone:	408-262-2665
Contact Name:	Kishore Kumar
Date Summary was Prepared:	January 10, 2005
Trade or Proprietary Name:	VitalWare VMS
Common or Usual Name:	Physiological Transmitter and Receiver
Classification Name:	Radiofrequency physiological signal transmitter and receiver.

Predicate Devices:

Device Name	510(k) Number
Argus System – Continuous Expert Care Network (modification of K001972 -10/27/00)	K012171
MPT 24 and Vital View 24	K000276
VitalCom Network Monitoring System	K041741

Description:
The TeleVital VitalWare VMS is a software system utilized for the real-time collection, storage, transmission, surveillance and management of vital sign data. The system can be used with any supported monitoring device or ancillary system connected directly to a PC computer or a network. The vital sign data is made available on any workstation on the network and/or Internet allowing health care professionals at the point of care to receive assistance from a supplementary care location. A typical deployment is composed of more than one PC workstation connected to one or more servers, receiving data from one or more medical devices over a network.

Intended Use:

The TeleVital VitalWare VMS is a vital sign monitoring and patient information software product intended to be used in conjunction with independent monitoring devices, and ancillary systems for the real-time collection, storage, and transmission to remote viewing sites.

The system intended to be used in a hospital or clinic environment. Clinical judgment

and experience are required to check and interpret the information delivered. VitalWare VMS is not intended to, and is not capable of controlling any of the medical devices it interfaces with.

Substantial Equivalence Summary:

VitalWare VMS software is similar to the predicates in that it has the same intended use, modes of operation, features and specifications. All devices are intended for the real-time capture, management and display of vital sign and patient medical information over a networked healthcare environment.

Testing & Performance Data:
Verification and validation activities were conducted to establish the performance and reliability characteristics of the VitalWare VMS device. Testing involved tests based on product specifications, safety testing based on risk analysis, and usability tests within an Inpatient Intensive Care Unit and an Outpatient Clinic environment.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications, of the VitalWare product with those of the predicate demonstrates that VitalWare VMS is substantially equivalent to existing products on the market today. Results of defined and controlled testing against its stated specifications and results gathered from hospital and clinic validation studies conducted in two states provides a very high confidence level that the device is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Televital, Inc.
c/o Grace Bartoo, Ph.D., RAC
Decus Biomedical, LLC
409 Walnut Street
San Carlos, CA 94070

Re: K050128
Trade Name: VitalWare VMS
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receivers
Regulatory Class: II (two)
Product Code: DRG
Dated: April 15, 2005
Received: April 18, 2005

Dear Dr.. Bartoo:

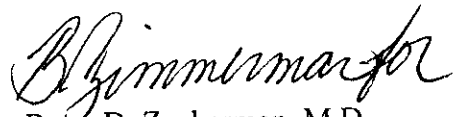
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 may be obtained 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050128

Device Name: VitalWareVMS

Indications for Use:

The TeleVital VitalWare VMS is a vital sign monitoring and patient information software product intended to be used in conjunction with independent monitoring devices, and ancillary systems for the real-time collection, storage, and transmission to remote viewing sites.

The system is intended to be used in a hospital or clinic environment. Clinical judgment and experience are required to check and interpret the information delivered. VitalWare VMS is not intended to, and is not capable of controlling any of the medical devices it interfaces with.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050128