MAY 27 2004

K040581

APPENDIX 6: 510 (K) SUMMARY

510(k) Summary
As required by 807.92
For MedVizer™ ViTel*Care* Patient Monitoring System
Prepared on February 16, 2004

Submitted by: ViTel Net
8201 Greensboro Drive, Suite 820
McLean, VA 22102

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

Contact Person: Allen Izadpanah
President and Chief Executive Officer

Device Trade Name: MedVizer™ ViTel*Care* Patient Monitoring System

Common Name: patient monitoring system

Classification: Not classified

Predicate Device: MedVizer™ PACS (K000557)

Manufactured by: ViTel Net
8201 Greensboro Drive, Suite 820
McLean, VA 22102

Description of the Device: MedVizer™ ViTel*Care* 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 the Device: MedVizer™ ViTel*Care* Patient Monitoring System is intended for use in the acquisition, communication, storage, display, and printing of video images and patient monitoring data.

Substantial Equivalence to Predicate Device: MedVizer™ ViTel*Care* Patient Monitoring System is virtually identical to MedVizer™ PACS. There are no technical differences with any implications for safety and effectiveness. The labeling of MedVizer™ ViTel*Care* Patient Monitoring System includes extensive protocols for monitoring patients with specific 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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2004

Visual Telecommunications Network, Inc.
c/o Mr. Roger Schneider
8201 Greensboro Drive, Suite 820
McLean, VA 22102

Re: K040581
Trade Name: MedVizer ViTel*Care* Patient Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: DQA
Dated: May 07, 2004
Received: May 12, 2004

Dear Mr. Schneider:

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) 594-4646. 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,

Neil R.P. Ogden for

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

Enclosure

Attachment 5

Indications for Use

510(k) Number (if known): _____

Device Name: **MedVizer™ ViTel*Care* Patient Monitoring System**

Indications for Use: MedVizer™ ViTel*Care* 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™ ViTel*Care* Call Center where a qualified healthcare practitioner can review the patient information and data. The healthcare practitioner can contact the patient directly through a videoconference connection when desired. 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.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040581

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)