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510(k) Summary of Safety and Effectiveness

Date: June 1, 2003

Submitter: Patient Monitoring Division
Datascope Corp.

Contact Person: Susan E. Mandy
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Patient Monitoring Division
Datascope Corp.
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Device trade name: ViewPoint Telemetry System

Common/usual name: Cardiac Arrythmia Monitor

Classification names: 21 CFR 870.2300- Cardiac monitor
21 CFR 870.1025- Arrhythmia detector and alarm
21 CFR 870.2910- Radiofrequency physiological signal transmitter and receiver

Predicate Devices: K021681 Micropaq Vital Signs Monitor
K022453 Acquity Central Monitoring Station
K020524 PatientNet Monitoring System

Device Description: The ViewPoint Telemetry System is an expansion to the ViewPoint Central Monitoring System, previously cleared by FDA under K011540. There have been no significant changes to ViewPoint Central Monitoring System since its clearance. The standard configuration of the ViewPoint Central Monitoring System consists of the ViewPoint Central Station, network printers, displays, keyboard, speakers, universal power supply and a mouse.

The ViewPoint Telemetry System is an ambulatory monitoring system that is designed to be used in the hospital/clinical environment to acquire and transmit ECG data derived from wireless physiological monitor(s) via RF telemetry transmitter(s) and receiver(s). The ViewPoint Telemetry System consists of three components: the ViewPoint Server (Server), Access Point, and ViewPoint Telepack 2.4 (Telepack). The ViewPoint Telemetry System uses the capability of bi-directional communication with the Server, via an Access Point network installed throughout the specified coverage area. These Access Points interface with the Server through an Ethernet connection. The Server does not collect data directly from patients; rather, it receives data through the Access Point from monitors, such as a Telepack, performs ST/Arrhythmia analysis, and then forwards it to the ViewPoint Central Station.

The Telepack communicates ECG signals and control/status messages to the Server through an Access Point utilizing the 2.4 GHz ISM wireless band, via a frequency hopping spread spectrum transmission technique. The Telepack is battery powered to allow for patient mobility.

Intended Use: As stated in Section 2, the expanded Indication for Use of the ViewPoint Central Monitoring System is the inclusion of the ViewPoint Telemetry System as follows:

The ViewPoint Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ViewPoint Telemetry System is intended for installation in the hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored include ECG, Heart Rate from ECG, Lethal and Non-Lethal Arrhythmia Detection and ST Segment Analysis. Received data is sent to the ViewPoint Server for ECG processing via Ethernet. This information can be displayed, trended, stored, and printed at the ViewPoint Central Station.

Technology: The ViewPoint Telemetry System is substantially equivalent to the Welch Allyn Micropaq, Welch Allyn Acquity Central Monitoring Station and GE Medical Systems PatientNet Monitoring System. The predicate systems are capable of monitoring ECG in ambulatory patients, as well as detecting lethal and non-lethal arrythmias, and analyzing ST segments.

Test Summary: The ViewPoint Telemetry System, complies with the voluntary standards identified in section six of this submission. Datascope's product development process required that the following activities be completed during the development of the ViewPoint Telemetry System:

- Requirements specification review
- Hardware and software testing
- Code design and code reviews
- Environmental/EMC testing
- Safety testing
- Performance testing
- Hardware and Software validation

Conclusion: The results of all testing demonstrate that the ViewPoint Telemetry System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Datascope Corporation
c/o Ms. Susan E. Mandy
Director, Clinical and Regulatory Affairs
Patient Monitoring Division
800 MacArthur Blvd.
Mahwah, NJ 07430

Re: K031760
Trade Name: ViewPoint Central Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (arrhythmia detector and alarm)
Regulatory Class: Class III (three)
Product Code: MHX
Dated: September 5, 2003
Received: September 8, 2003

Dear Ms. Mandy:

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 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,

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

Enclosure

K031760

Indication for Use

ViewPoint Central Monitoring System: (K011540)

The Indications for use for the ViewPoint Central Monitoring System include:

- Viewing real time patient clinical and demographic data
- Graphical and numeric trending of clinical data
- Storing and printing of clinical and demographic data
- Setting independent alarm limits for data sent by the bedside monitor.

The clinical data displayed by the ViewPoint Central Monitoring System is obtained from one or more Datascope compatible physiological monitors and includes: ECG waveforms, Invasive and Non-Invasive Blood Pressure, Blood Oxygenation (SpO2), Heart Rate, Respiration Rate, Temperature, CO2 inspired and end-tidal, Ventricular Arrythmia analysis and ST Segment analysis.

The ViewPoint Central Monitoring System is intended for use in a fixed location, in the health care facility setting, as a central viewing station. The ViewPoint Central Monitoring System is not intended to be directly connected to the patient at any time, or installed in a patient's vicinity.

ViewPoint Telemetry System:

The ViewPoint Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ViewPoint Telemetry System is intended for installation in the hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored include ECG, Heart Rate from ECG, Lethal and Non-Lethal Arrhythmia Detection and ST Segment Analysis. Received data is sent to the ViewPoint Server for ECG processing via Ethernet. This information can be displayed, trended, stored, and printed at the ViewPoint Central Station.

Melissa May for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031760