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K001308 p 1/4

Zymed

Zymed Inc.
1201-B N. Rice Ave.
Oxnard, California 93030
800.235.5941 - 805.604.0457
Fax 805.604.0493

510(k) Summary

Submitter:

Gretel Lumley, Quality Assurance Engineer
Zymed Medical Instrumentation
1201 B North Rice Avenue
Oxnard, CA 93030
Fax: 805/604-0493
Phone: 800/235-5941 (417)
Date of Summary: 4/24/00
Contact: G. Lumley – see above

Trade Name: Zymed Telemetry System: Model EasiView
Common Name: Telemetry Central Station Monitor
Classification Name: Detection and Alarm, Arrhythmia
(per 21 CFR 870.1025)

Legally marketed device to which S.E. is claimed.
Zymed Telemetry System: Model EasiView – 510(k) K 980186
Marquette Medical Systems, Inc: APEX Oximeter – 510(k) K980299
Nonin Medical, Inc.: NONIN Pulse Oximeter amd Carbon Dioxide Detectors: model 9840-Series – 510(k) K982969

Description: A Zymed Telemetry monitoring system consists of a series of interface devices to include ECG transmitters, SPO2/ECG transmitters, a central Telemetry monitoring computerized unit with a strip chart recorder, Easi 5 lead and laser printer. The Zymed central monitor supports up to eight patients for real time cardiac monitoring. The system displays each patient's ECG continuously on the screen while performing real time ECG waveform analysis for all eight patients. This analysis permits immediate detection and classification of abnormal beats, cardiac rhythm disturbances and variations. The system will also display each patient's Oxygen Saturation.

Each ECG transmitter's frequency can be programmed to operate at any frequency within the entire VHF band. For US domestic sites, the transmitters will comply with FCC band allocations (174-216 Mhz). In addition to ECG data, the transmitters also detect and transmit cardiac pacemaker information. Other information including transmitter status and individual lead impedance is also transmitted to the Zymed system for overall system safety and efficacy.

The Zymed system presents the user with a number of clinical tools such as visual and audible alarms for the diagnosis of patients with various heart conditions. The system also provides tools to review a patient's cardiac performance. On-line review mechanisms as well as detailed analysis screens have been designed into the system to facilitate and to enhance the patient's diagnosis and treatment. Features such as individual ECG printouts, multi-channel automatic ST analysis, trend data analysis, and Full Disclosure data further enhance the system's qualities as a valuable and practical clinical tool.

The Zymed system presents the user with a number of clinical tools such as visual and audible alarms for multi-parameter monitoring of the patient. The Zymed system provides a means to monitor multiple patients from a central monitoring station for ECG and Oxygen Saturation.

The system has the following options available:

Choice of 4, 6, or 8 bed central monitor
Full disclosure screen and printout (full resolution programmable from 0 to 168 hours)
Choice of 6 lead sets, based on transmitter capability
Full arrhythmia analysis to include multi-channel automatic ST Analysis
Laser Printer, print server options
Strip Chart
Networking

Intended use:

- Assessment of symptoms that may be related to rhythm disturbances of the heart: Patients with palpitations; The evaluation of arrhythmia's in patients from pediatric to adult age.
- Assessment of risk in patients with or without symptoms of arrhythmia.
- Assessment of efficacy of Antiarrhythmic therapy.
- Assessment of Pacemaker Function.
- Assessment of real time ST segment analysis
- Assessment of symptomatic or asymptomatic patients, to evaluate for, ischemic heart disease and arrhythmia analysis during exercise testing.
- Assessment of transferred SpO2 data from an oximeter to EasiView for display and alarm.
- Assessment is for single-hospital environment.

A review of the technological characteristics compared to the predicate devices are:

Specification/Feature	**Predicate Telemetry Easiview System**	**Modified Telemetry Easiview System**
Type	IBM Compatible PC	Same
CPU	200 Mhz Pentium Pro or greater	Same
RAM	64 M Bytes or greater	Same
Hard Disk	1.6 G Bytes or greater	Same
Display	SVGA	Same
<u>Software:</u>		
Number of patients	4, 6, or 8	Same
Operating System	Windows NT	Same
	DOS Compatible	Same
Data Storage	24 hrs of EKG/Channel	Same
Number of leads for Analysis:	3	Same
Automatic ST Analysis	yes	Same
Manual ST Analysis	no	no

Specification/Feature	Predicate Telemetry Easiview System	Modified Telemetry Easiview System
Transmitter Platform:		
Type	Embedded processor and RF PCBA	Same
Microcontroller	PIC16C74	PIC16C67
RAM	128 bytes	368 bytes
Program memory	2K bytes	4K bytes
Display	None	Alphanumeric LCD
User input device	Nurse call button	Keypad with 4 keys
Battery source	2 AA alkaline	Same
Data acquisition:		
ECG	3 channels	Same
Pacer capture	Logical OR CH1 and 2	Same
Frequency response	.05-40 Hz, programmable	Same
SPO2 data	None	Numeric (uses Nonin Module)
RF tramsmission:		
Tunable frequencies	174-216 MHz, (entire VHF range)	Same
Transmission range	50 ft. without distributive antenna system	Same
Failsafe and alert signals transmitted to Easiview:		
Nurse Call	Yes	Same
Battery voltage	Yes	Same
Low battery alert	Yes	Same
Lead voltage	Yes	Same
Loose lead alert	Yes	Same
Input signal saturation	Out of range indicator	Same
Tuned frequency	Yes	Same
Type of data transmitted	Transmitter ID	Same
	Software revision	Same
SPO2 module status	Non applicable	Yes

Specification/Feature	Predicate MDE Escort Monitor System	Modified Telemetry Easiview System
SpO2		
Range	20 – 100%	Same
Accuracy	Adult 70 – 100% +/- 2%	Same
	50 - 69% +/- 3%	Same
	Neonatal 70 - 94% +/- 3%	Same
Pulse rate range	35-250 BPM	Same
Pulse rate accuracy	+/- 3 BPM	Same
Alarms	70 - 100% high limit	0 – 100 % by 1%
	50 - 99% low limit	0 – 100 % by 1%

Performance was measured against industry accepted AHA (AHA), MIT (MIT) and European ST-T (EST) databases. Results were typical for the real time monitoring environment for the EasiView as targeted. Separate sensitivities (SE), positive predictivity (+P), and false positive rate (FPR) were examined for each database and measured for QRS, Ventricular, Couplets, Short runs and Long runs. Separate Episode Sensitivities (ESE), Episode Positive Predictivity (E+P), Duration Sensitivity (DSE) and Duration Positive Predictivity (D+P) were examined for the European ST-T(EST) database and measured for ST analysis. High heart rates to include pediatric patients were demonstrated to be within recommended guidelines in excess of 300 bpm, and performance in the presence of noise indicates the new system is equal to or better than the old system when looking at baseline, electrode or muscle as the cause of noise.

In summary, performance data between the two systems shows nearly identical data, and therefore, supports a claim of Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 7 2000

Ms. Gretel Lumley
Quality Assurance Engineer
Zymed Inc.
1201-B North Rice Avenue
Oxnard, CA 93030

Re: K001308
Zymed Telemetry System: Model EasiView
Regulatory Class: III (three)
Product Code: DSI, DQA
Dated: April 24, 2000
Received: April 25, 2000

Dear Ms. Lumley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K001308

Device Name: EasiView Telemetry Monitoring System

Indications for Use:

- Assessment of symptoms that may be related to rhythm disturbances of the heart; Patients with palpitations; The evaluations of arrhythmia's in patients from pediatric to adult age.
- Assessment of risk in patients with or without symptoms of arrhythmia.
- Assessment of efficacy of Antiarrhythmia therapy.
- Assessment of Pacemaker Function.
- Assessment of real time ST segment analysis.
- Assessment of symptomatic or asymptomatic patients, to evaluate for, ischemic heart disease and arrhythmias analysis during exercise testing.
- Assessment of transferred SpO2 data from an oximeter to EasiView for display and alarm.
- Assessment is indicated for single-hospital environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001308

Prescription Use X
(CFR21 CFR 801.109)

or

Over-The-Counter Use ____