K 980186

OCT 7 1998

Zymed

Zymed Inc
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Camarillo, California 93010-83
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510(k) Summary

Submitter

Dudley Harris, Director of Regulatory Affairs/QA
Zymed Medical Instrumentation
20 North Aviador Street
Camarillo, CA 93010
Fax: 805/987-9532
Phone: 800/235-5941 (401)
Date of Summary: 10-06-98
Contact: D. Harris – 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 951370
Zymed Holter Scanning System: Model 2010 – 510(k) K 930806

Description: A Zymed Telemetry monitoring system consists of a series of interface devices to include ECG transmitters, a central Telemetry monitoring computerized unit with a strip chart recorder, Easi 5 (12 lead derived), 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.

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 and derived 12 lead display 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 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
12 lead ECGD
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 is for single-hospital environment.

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

Platform	EasiView (New) *telemetry system*	EasiView (Old) *telemetry system*	Holter *holter system*
Type	IBM PC AT Compatible	Same	
CPU	200 Mhz Pentium Pro	486/66 Mhz	
RAM	64 M Bytes	64 M Bytes	
Hard Disk	1 6 G Bytes	1.2 G Bytes	
Display	SVGA	Same	
Transmitters:			
3 channel	yes	yes	
Tunable frequencies	174-216 Mhz	Same	
Software			
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	no	no
Manual ST Analysis	no	no	yes

The only difference between the two Zymed systems is the addition of automatic Multi-channel ST Analysis/alarm to the algorithm.

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. 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

OCT 7 1998

Mr. J. Dudley Harris
Zymed Inc.
20 North Aviador Street
Camarillo, CA 93010-8348

Re: K980186
EasiView Telemetry Monitoring System - Modified with ST-Segment Analysis
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: July 20, 1998
Received: July 21, 1998

Dear Mr. Harris:

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 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 (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"(21 CFR 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K980186

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 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 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)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____
(CFR21 CFR 801.109)