

FEB 8 1999

K984089
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Zymed

Zymed Inc.
20 North Aviator Street
Camarillo, California 93010-5148
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510(k) Summary

Submitter:

Dudley Harris, Director of Regulatory Affairs/QA
Zymed Medical Instrumentation
20 North Aviator Street
Camarillo, CA 93010

Fax: 805/987-9532
Phone: 800/235-5941 (401)
Date of Summary: 12-3-98
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 980186

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.
- Assessment of EASI derived 12-lead ST measurements is recommended for patients that meet the following parameters.
 1. Ages: 33 to 82 years
 2. Heights: 147 to 185 cm (58 to 73 in)
 3. Weights: 53 to 118 kg (117 to 261lb)
 4. Height to Weight Ratios: 1.41 to 2.99 cm/kg (0.25 to 0.54 in/lb.)

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

<u>Platform</u>	<u>EasiView (New)</u> <i>telemetry system</i>	<u>EasiView (Old)</u> <i>telemetry system</i>
Type	IBM PC AT Compatible	Same
CPU	200 Mhz Pentium Pro	Same
RAM	64 M Bytes	Same
Hard Disk	1.6 G Bytes	Same
Display	SVGA	Same
<u>Transmitters:</u>		
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, 12 derived leads	yes, 3 leads
Manual ST Analysis	no	no

The only difference between the two Zymed systems is the extension of automatic ST Analysis to the derived 12 lead.

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.

FEB 8 1999

K984089

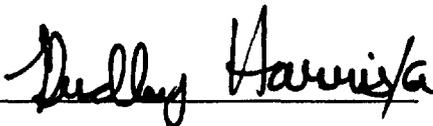
Zymed

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TRUTHFUL AND ACCURATE STATEMENT

**PREMARKET NOTIFICATION AND ACCURATE STATEMENT
(As required by 21 CR 807.87(1))**

I certify that, in my capacity as Director of Regulatory Affairs/Quality Assurance, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



J. Dudley Harris

11/13/98

Dated

J. Dudley Harris
Director Regulatory Affairs
Quality Assurance
Phone: 800/235-5941
Fax: 805/987-9532



FEB 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dudley Harris
Director Regulatory Affairs/Quality Assurance
Zymed Inc.
20 North Aviator Street
Camarillo, CA 93010-8348

Re: K984089
Trade Name: Zymed Telemetry System, Model Easi View
Regulatory Class: III
Product Code: DSI
Dated: November 13, 1998
Received: November 16, 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

Page 2 - Mr. Dudley Harris

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) 594-4586. 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,



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: K984089

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984089

Prescription Use
(CFR21 CFR 801.109)

or

Over-The-Counter Use