

JUL 28 1999

K992197

Zymed

Zymed Inc.
20 North Aviator Street
Camarillo, California 93010-8348
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510(k) Summary

Submitter:

Gretel Lumley, Quality Assurance Engineer
Zymed Medical Instrumentation
20 North Aviator Street
Camarillo, CA 93010

Fax: 805-987-9532
Phone: 800-235-5941 (417)
Date of Summary: 6-29-99
Contact: G. Lumley – see above

Trade Name: Zymed Holter 2000 - Software
Common Name: Holter Analyzer
Classification Name: Electrocardiograph, Ambulatory, with Analysis Algorithm
(per 21 CFR 870.2800)

Legally marketed device to which S.E. is claimed.
Holter 2000 – 510(k) 990170

Description: The Holter 2000-Software is a device that when installed onto a user's Hardware platform, will convert their system into a Holter scanner analyzes recorded cardiac ECG and creates reports from the recorded data. The patient's ECG is pre-recorded onto one of several data storage mediums, which is fed into user's Holter system whereby the Holter 2000 software analyzes the ECG and provides reports on a variety of cardiac data. The cardiac data that is analyzed is individual ECG waveforms and patterns of consecutive waveforms. Cardiac data provided by Zymed's Holter 2000-Software is used by trained medical personnel to diagnosis patients with various cardiac rhythm patterns.

The Zymed software system presents the user with a number of clinical tools such as ECG report generation. The system also provides tools to review a patient's cardiac performance. Features such as individual ECG printouts, multi-channel automatic ST analysis, multi-channel morphology analysis and Custom Reports further enhance the system's qualities as a valuable and practical clinical tool.

The system has the options available:
Full Arrhythmia analysis to include multi-channel automatic ST Analysis
12 lead ECGD
Data Acquisition on 2 or 3 Channels
Digital Input

Indications for Use:

1. **Assessment of symptoms that may be related to Rhythm Disturbances of the Heart in patients from pediatric to adult age. Patients with palpitations.**
2. **Assessment of risk in Patients With or Without Symptoms of Arrhythmia. Patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patient with left ventricular dysfunction using arrhythmia e.g.: ventricular ectopy, as method of risk assessment.**
3. **Assessment of Efficacy of Antiarrhythmic Therapy. Patients with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes supraventricular arrhythmia or ventricular tachycardia.**
4. **Assessment of Pacemaker Function. Evaluation of patients with paroxysmal symptoms, detection of myopotential inhibition, detection of pacemaker mediated tachycardia, evaluation of antitachycardia pacing device function, evaluation of rate-responsive physiological pacing function.**
5. **Detection of Myocardial Ischemia. Patients with chest pain suggestive of Prinzmetal's angina.**

Review of Technology characteristics compared to the predicate device:

<u>Platform</u>	<u>Holter 2000 (Predicate)</u> <i>Holter</i>	<u>Holter 2000-Software</u> <i>Holter</i>	
Type	IBM PC AT Compatible	Same	} Hardware Supplied by User to published minimum specification.
CPU	200 Mhz Pentium Pro or greater	Same	
RAM	64 M Bytes Minimum	Same	
Hard Disk	540 M Bytes Minimum	Same	
Display	SVGA	Same	
 <u>Data Acquisition</u>			
Number of Channels	2 or 3	Same	
Resolution	8 bits	Same	
Sampling Frequency	192 samples per second	Same	
Digital Input	Yes	Same	
 <u>Software</u>			
Operating System	Windows NT	Same	
ST Segment Analysis	Yes	Same	

The only difference between the two Zymed systems is that one system is supplied as a complete system while the other is a software only package.

Performance was measured against industry accepted AHA (AHA), MIT (MIT) and European ST-T (EST) databases. Results were typical for the Holter 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 equivalent to 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

JUL 28 1999

Ms. Gretel Lumley
Quality Assurance Engineer
Zymed, Inc.
20 North Aviator Street
Camarillo, CA 93010-8302

Re: K992197
Modification to Zymed Holter 2000
Regulatory Class: II (two)
Product Code: MLO
Dated: June 29, 1999
Received: June 30, 1999

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 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 (Pre-market 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,



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: K992197

Device Name: Zymed Holter 2000

Indications for Use:

- Assessment of symptoms that may be related to rhythm disturbances of the heart in patients from pediatric to adult age. Patients with palpitations.
- Assessment of risk in Patients With or Without Symptoms of Arrhythmia. Patients with symptomatic or asymptomatic idiopathic hypertrophic cardiomyopathy and postmyocardial infarction patient with left ventricular dysfunction using arrhythmia e.g.: ventricular ectopy, as method of risk assessment.
- Assessment of efficacy of Antiarrhythmia Therapy. Patients with baseline high frequency, reproducible, sustained, symptomatic premature ventricular complexes supraventricular arrhythmia or ventricular tachycardia.
- Assessment of Pacemaker Function. Evaluation of patients with paroxysmal symptoms, detection of myopotential inhibition, detection of pacemaker mediated tachycardia, evaluation of antitachycardia pacing device function, evaluation of rate-responsive physiological pacing function.
- Detection of Myocardial Ischemia. Patients with chest pain suggestive of Prinzmetal's angina.

(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 Sleep Medicine

CDRH, ODE

K992197

Prescription Use (CFR21 CFR 801.109)

or

Over-The-Counter Use