K970298

AUG 20 1997

SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

19.1 SUBMITTER INFORMATION

a.	Company Name:	Diagnostic Monitoring
b.	Company Address:	1176 Main Street, Bldg. C Irvine, CA 92614
c.	Company Phone:	(714) 568-1695
d.	Contact Person:	Raymond Cohen President
e.	Date Summary Prepared:	May 21, 1997

19.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	DM-400™ Holter ECG Cassette Recorder
b.	Classification Name:	Medical Magnetic Tape Recorder

19.3 IDENTIFICATION OF PREDICATE DEVICE(S)

Company	Device	510(k) No.	Date Cleared
Datrix	XR-300 Holter ECG Recorder	K921068	March 30,1992
Zymed	MultiTrak Ambulatory ECG Recorder	K930894	November 11, 1993

19.4 DEVICE DESCRIPTION

The Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder is a battery operated ambulatory ECG recording device. The DM-400 Holter Recorder is capable of recording three independent channels of ECG from an ambulatory patient. The patient is connected to the recorder by means of a 5 or 7 wire bonded lead set and silver/silver chloride self adhesive electrodes. The DM-400 Holter Recorder can perform either a 24 or 48 hour ECG recording. The recorder is equipped with self calibration and a patient event signal button.

19.5 SUBSTANTIAL EQUIVALENCE

The Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder is substantially equivalent to other ambulatory ECG recorders currently in commercial distribution by Datrix and Zymed in terms of the intended use of achieving a safe and accurate ECG recording of an ambulatory patient. The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison charts provided in Section 19.7 .

19.6 INTENDED USE

The DM-400 Holter ECG Cassette Recorder is a device designed for ECG recording of an ambulatory patient.

19.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices is provided in the following device comparison charts. Finished product

specifications, schematic drawings and detailed description of the device have been provided.

The Device Comparison Chart #1 provides a side by side comparison of the characteristics of the Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder and the Datrix XR-300 Holter ECG Recorder.

Device Comparison Chart #2 provides a side by side comparison of the characteristics of the Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder and the Zymed MultiTrak Ambulatory ECG Recorder.

As evidenced by the comparison charts the DM-400 Holter Recorder and the predicate devices are similar in their function and characteristics. There are no differences between the technologies which require further evaluation.

DEVICE COMPARISON CHART #1

Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder & Datrix XR-300 Holter ECG Recorder

Manufacturer	Diagnostic Monitoring	Datrix
Model No.	DM-400 Holter ECG Recorder	XR-300 Holter ECG Recorder
Intended use	ECG recording of ambulatory patients.	ECG recording of ambulatory patients.
Design		
-portable	Yes	Yes
-power source	9V alkaline battery	9V alkaline battery
-cassette tape	standard C60	standard C60
-number of heads	1	1
-channels	4 (3 ECG, 1 timing track)	4 (3 ECG, 1 timing track)
-tape speed	1.0mm/sec	1.0mm/sec
- recording time	24 or 48 hours	25 hours, nominal
- frequency response	0.05 to 100 Hz (-3dB)	0.05 to 100 Hz (-3dB)
-common mode rejection	60 dB minimum 1 volt peak-to-peak 60 Hz common mode signal	60 dB minimum 1 volt peak-to-peak 60 Hz common mode signal
-electrolead cables	5 or 7 lead	5 or 7 lead

DEVICE COMPARISON CHART #1

Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder & Datrix XR-300 Holter ECG Recorder

Manufacturer	Diagnostic Monitoring	Datrix
Features		
-patient event button	Yes	Yes
-built-in calibration	Yes	Yes
-carrying case	Yes	Yes
-color coded ECG outputs	Yes	Yes

DEVICE COMPARISON CHART #2

Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder & Zymed MultiTrak Ambulatory ECG Record

Manufacturer	Diagnostic Monitoring	Zymed
Model No.	DM-400 Holter ECG Recorder	MultiTrak Ambulatory ECG Recorder (3 channel configuration)
Intended use	ECG recording of ambulatory patients.	ECG recording of ambulatory patients.
Design		
-portable	Yes	Yes
-power source	9V alkaline battery	9V alkaline battery
-cassette tape	standard C60	Phillips C60 or C90
-number of heads	1	1
-recording channels	4 (3 ECG, 1 timing track)	4 (3 ECG, 1 timing track)
-tape speed	1.0mm/sec	1.0mm/sec
- recording time	24 or 48 hours	36 hours
- frequency response	0.05 to 100 Hz (-3dB)	0.05 to 100 Hz (-3dB)
-common mode rejection	60 dB minimum 1 volt peak-to-peak 60 Hz common mode signal	60 dB minimum
-electrolead cable	5 or 7 lead	5 or 7 lead

DEVICE COMPARISON CHART #2

Diagnostic Monitoring DM-400 Holter ECG Cassette Recorder & Zymed MultiTrak Ambulatory ECG Recorder

Manufacturer	Diagnostic Monitoring	Zymed
Features		
-patient event button	Yes	Yes
-built-in calibration	Yes	Yes
-input protection for defibrillator	Yes	Yes
-carrying case	Yes	Yes

19.8 PERFORMANCE DATA

The DM-400 Holter ECG Cassette Recorder has been demonstrated to perform as intended with accuracy and repeatability. A summary of the performance testing of the DM-400 Holter Recorder are presented in the following.

The DM-400 Holter ECG Cassette Recorder was tested for functionality and adherence to design specifications. The testing encompassed the major functional and specialized features of the DM-400 Recorder. Testing included verification of the power supply and low battery features, complete circuitry testing, verification of the unit calibration, ECG amplifier verification, testing of the event signals, baseline centering, frequency response testing, common mode rejection and Motor Controller Circuit operation. In addition, dynamic testing of the units was performed to assure that the electronic package functions correctly with the supplied mechanical package. A 24 hour Calibration test was performed, as well as a visual inspection of the unit and a scanning verification.

Results of the testing showed that the DM-400 Holter ECG Recorder units met the design specifications and performed as intended. Repeatability testing of the units showed that the DM-400 Recorder provides consistent results. Testing of the DM-400 Recorder verifies that the device is designed for accurate and safe ECG recording of an ambulatory patient. The testing also confirms that the features and characteristics of the DM-400 Recorder device perform within the expected parameters of the substantially equivalent devices with the same features and characteristics.

19.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Raymond Cohen
Diagnostic Monitoring™
1176 Main Street, Building C
Irvine, California 92614

AUG 20 1997

Re: K970298
DM-400 Holter ECG Cassette Recorder
Regulatory Class: II (two)
Product Code: 74 DSH
Dated: May 22, 1997
Received: May 23, 1997

Dear Mr. Cohen:

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 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/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

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Diagnostic Monitoring DM-400 Holter ECG Recorder

Indications For Use: The DM-400 Holter ECG Cassette Recorder is a device designed for ECG recording of an ambulatory patient.

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 K970298

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)