

APPENDIX A-1

510(K) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS

1. SUBMITTER INFORMATION

Company: Datrix
 Address: 316 State Place
 Escondido, CA 92029

 Phone: (760) 480-8874
 Fax: (760) 480-9474

 Contact Person: Jon Barron

 Date Prepared: August 21, 1998

2. DEVICE INFORMATION

Trade Name: DR512 Digital ECG Holter Recorder
 Common Name: Ambulatory ECG Recorder
 Classification Name: Recorder, Magnetic Tape, Medical

3. PREDICATE DEVICES

<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Datrix XR300 ECG Holter Recorder	K921068	March 30, 1992
Braemar DL700 Digital ECG Holter Recorder	K945130	April 4, 1998

4. DESCRIPTION

The DR512 is a lightweight, compact, digital Holter recorder designed for ambulatory ECG applications. Three channels of ECG data are collected via a 5 or 7 lead wire set and silver-chloride electrodes. The recorder is battery powered to ensure electrical isolation of

enclosure coated with an electromagnetic interference spray. The DR512 has internal calibration, and a patient activated event marker button. ECG data are collected for 24 hours.

5. INTENDED USE

The DR512 digital Holter recorder is intended for the recording and storage of long-term ECG data collected from ambulatory patients. The recorder is used under the order of a physician, who reviews the data after downloading and processing by a Holter playback system. The physician determines the presence of normal and abnormal ECG data during the events of the patient's daily activity.

6. SUBSTANTIAL EQUIVALENCE

The DR512 is substantially equivalent to other commercially distributed ECG Holter recorders. The fundamental technical characteristics of the DR512 are similar to those of the predicate devices: all are 3-channel, record for 24 hours, and have similar standards and specifications. The main difference between the XR300 and the DR512 is the storage media. While the analog technology of the XR300 uses a cassette tape to store the data, both the DR512 and DL700 use digital flash disk technology. The technical characteristics of each recorder are summarized in the following chart.

SPECIFICATION	DATRIX DR512	DATRIX XR300	BRAEMAR DL700 *
FUNCTIONAL			
ECG CHANNELS	3	3	3
RESOLUTION	8 BIT	ANALOG	8 BIT
SAMPLE RATE	128 TO 512/CHAN/SEC	ANALOG	128 TO 140/CHAN/SEC
RECORDING DURATION	24 HOURS	24 HOURS	24 HOURS
PHYSICAL			
OPERATING POSITION	ANY	ANY	ANY
SIZE (in)	4.94 x 2.75 x .94	6 x 3.5 x 1.12	6 x 3.5 x .95
WEIGHT	4 ounces	13 ounces	10 ounces
ENCLOSURE MATERIAL	Plastic	Plastic	Plastic
ENVIRONMENTAL			
OPERATING TEMP	0 to 60 degrees C**	+5 to 45 degrees C	0 to 45 degrees C
OPERATING HUMIDITY (non condensing)	8% to 95%**	10% to 90%	10% to 90%
OPERATING ALTITUDE	8000 feet	8000 feet	10000 feet
OPERATING SHOCK	26 inch drop in pouch	18 inch drop in pouch	3 inch drop

SPECIFICATION	DATRIX DR512	DATRIX XR300	BRAEMAR DL700 *
ELECTRICAL			
BANDWIDTH	.05 to 50 Hz	.05 to 100 Hz (-3dB)	.05 to 50 Hz
SIGNAL INPUT RANGE	5 mV >5 Meg	5 mV >5 Meg	5 mV >5 Meg
INPUT IMPEDANCE			
COMMON MODE REJECTION RATIO (60HZ SIGNAL)	60 dB	60 dB	60 dB
POWER REQUIREMENTS			
BATTERY	One 9 Volt	One 9 Volt	Two AA
AVERAGE OPERATING CURRENT	5 mA	5 mA	35 mA
PEAK OPERATING CURRENT	55 mA	5 mA	330 mA

* Specifications taken from manufacturer's specification sheet

** Limited by flash card specifications

7. PERFORMANCE DATA

The DR512 digital ECG Holter recorder has been tested and shown to conform to design specifications. Verification of the analog hardware was comprised of testing the ECG amplifier frequency response, amplification, and common mode rejection ratio, as well as the voltage converter, event button circuits, and battery polarity. Visual inspection of all parts was also made. A RAM write-read test of the digital hardware was conducted using an emulator to verify that the RAM was functioning, the RAM data, address, and control lines were connected correctly, and that the microcontroller was functioning. The recorder firmware was tested for flash disk control, A/D conversion and sampling rate, compression-decompression. The compression-decompression algorithms were tested with line segment data, calibration signals, and simulated ECG waveforms. The recorder was validated using both bench and subject testing. The recorder was also independently tested and shown to be compatible with commercially available playback systems.

Extensive troubleshooting was conducted to ensure that the recorder responded appropriately to improper use of the recorder. These tests included improper insertion of the flash card, improper termination of recording, improper insertion of the battery, and low battery. The beeps indicating proper functioning of the recorder were also tested.

Environmental tests were conducted to verify the operating ranges for temperature, humidity, and altitude. Shock and EMC testing were also conducted.

Results of all testing indicated that the DR512 digital Holter recorder is an accurate and consistent device, with repeatable performance. The recorder has been shown to perform to design specifications, and is suitable for ECG applications with ambulatory patients.

APPENDIX 2
YEAR 2000 STATEMENT

The DR512 will continue to function properly regardless of the date. All time functions of the DR512 are based on elapsed time from the start of recording. All of the devices used to test the DR512 have no date function, or have been tested to ensure that there is no effect on the quality or safety of the device.



NOV 10 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Jon Barron
DATRIX
316 State Place
Escondido, CA 92029Re: K982975
Digital ECG Holter Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: August 21, 1998
Received: August 26, 1998

Dear Mr. Barron:

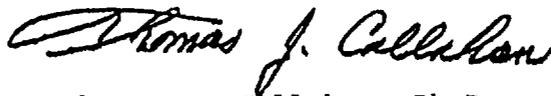
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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' (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,

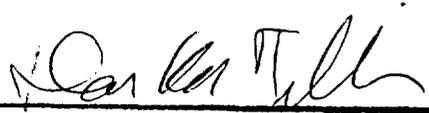


Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 STATEMENT OF INTENDED USE

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982925

~~Prescription Use~~ _____
(Per 21 CFR 801.109)