

510(k) Summary of Safety and Effectiveness

Intended Use

The Ambulatory X-12 Telemetry Module is designed to acquire, transmit, and receive diagnostic quality ECG data while allowing the patient to be ambulatory in a clinical setting. It can be used with any population, provided a standard torso 12-lead hook-up is used.

Device Description

The Ambulatory X-12 Telemetry Module, designed and manufactured by Mortara Instrument, Inc. represents the state-of-the-art in Wireless Electrocardiographic Technology. Design innovations implemented in the Ambulatory X-12 Telemetry Module achieve real-time acquisition, RF transmission of simultaneous 12-lead ECG data with diagnostic quality to the Mortara Receiver Module while allowing the patient to be ambulatory.

The Ambulatory X-12 Telemetry Module combines unparalleled accuracy, flexibility, and ease of use in a small light-weight Ambulatory X-12 (transmitter) unit worn by the patient. The patient cable used in conjunction with the Ambulatory X-12 is a light-weight flexible design, which plugs into a polarized connector on the side of the transmitter. The cable is worn by the patient in a standard torso 12-lead hook-up, and connects directly to snap type electrodes.

The Large LCD screen clearly displays each lead's status or lead fault. Two letter codes for Power On(On) and Low Battery (Lb) are displayed during normal operation, with the ON/OFF switch located inside the battery compartment, to prevent transmitter from being inadvertently turned off during normal use. When turned ON, the power to the Ambulatory X-12 is supplied by two size AA Alkaline batteries.

Lead Check Mode is initiated by the TEST button and the CALL button is used to select individual leads. Once in Lead Check Mode an LC code is displayed along with a flashing torso lead indicator of the lead being tested and a bar graph indicating the lead quality.

ECG data is gathered and transmitted on a low power, FM modulated carrier using a proprietary encoding scheme. An electrocardiograph containing the Mortara Receiver Module demodulates and decodes the data. The Ambulatory X-12 Telemetry Module affords the patient complete freedom of movement. Unlimited range can also be obtained with the addition of the Mortara Antenna Network Box(s).

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Mortara Antenna Network Boxes are placed at multiple locations within an installation. An antenna is properly combined onto the transmission line in the Mortara Antenna Network Box. The Mortara Antenna Network Box also has a 10dB of gain to counter the loss of long cables. To maintain good operating range anywhere along an antenna network the loss through the cables to the receiver is offset equally by the gain in the Antenna Network Box(s).

Each Mortara Antenna Network Box requires DC power. The power can either be applied to the front panel connector or supplied through the RF cables. When one box is supplied power, the other boxes in the network can receive power through the RF cables. Potentially, a long network can be supplied with a single power source with no additional cabling required. However if there are branches in the network this will require additional power sources. It is recommended to use a 9 to 12 volt DC supply.

Utilizing a single frequency band of 915 MHz or 2500 MHz, the Ambulatory X-12 is capable of transmitting on any one of 256 distinct, user selectable, channels. This allows multiple Ambulatory X-12's to operate in the same general area by simply selecting different channels for each transmitter.

Non-Clinical Performance Data

To ensure the safety and effectiveness of the Ambulatory X-12 Telemetry Module, verification and validation were performed in accordance with the following standards

AAMI EC 11-1991	Diagnostic Electrocardiographic Devices
AAMI -EC 38-1994	Ambulatory Electrocardiographs
IEC-601-1	Medical Electrical Equipment, Part 1: General Requirements for safety
IEC-601-1-2	Medical Electrical Equipment Part 1: General Requirements for Safety; 2. Collateral Standard: Electromagnetic Compatibility Requirements and Test
IEC-601-2-25	Medical Electrical Equipment Part 2: Particular Requirements for Safety of Electrocardiographs
UL 2601-1	Medical Electrical Equipment, Part 1: General Requirements for safety
FCC PART 15, Subpart C	FCC Rules and Regulations

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Comparison to Predicate Devices

Tabular Comparison of Competitor's Devices

	Mortara Instrument	Hewlett Packard M1403A Digital UHF Telemetry System 510k #: (K920429)	Marquette Electronics CD-Telemetry LAN 510k #: (K891104)
Features	Ambulatory X-12	HP M1400A Transmitter	CD Telemetry Transmitter
Intended Use	Transmit 12 leads of patient data by a digital radio transmission.	Transmit 2 leads of patient data by a digital radio transmission to a receiver over an antenna network to a Central Station.	Transmit 3 leads of patient data by a digital radio transmission to a receiver over an antenna network to a Centralscope
Target Population	Adults and Neonatal Patients	Adult or Neonatal Patients	Adult or Neonatal Patients
Product Labeling	Brochures and Operator's Manual	Brochures	Brochures
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	2 Leads transmitted	3 Leads Transmitted
Input Channels	Simultaneous acquisition of all 12 leads.	A three-electrode set for single-lead operation. A four or five-electrode set for dual-lead operation	5 Lead Configuration
Leads Connector	Single Block 10 lead	Single Block 3/4/5 leads	5 individual leads
Input Impedance	47 megohms	Greater than 10 megohms (below 60 Hz)	15 megohm min differential at 10 Hz

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Input Dynamic Range	700mV	± 8mV	± 5mV
Electrode Offset Tolerance	350mV	± 400mV	± 450mV
Signal Strength	Not Specified	30 meters with a signal strength of 8 mV/meter	Not Specified
Dimensions	5.52 x 2.65 x 1.00 in.	4.65 x 2.62 x 1.09 in	6.00 x 3.00 x 1.20 in
Weight (Transmitter)	6.7 oz (without batteries) 8.3 oz (with batteries)	6.9 oz (with batteries)	12 oz (unknown with/without batteries)
Case Material	High-impact ABS	High-impact ABS/polycarbonate and polypropylene	High carbon antistatic plastic
Performance Testing	EC-38-1994 EC-11-1991	Not Specified	Not Specified
Digital Sampling	500 s/sec/channel transmission for recording and analysis	Not Specified	120 samples/sec
Special Functions	Pacemaker detection and transmission; Lead off detection and transmission; Electrode impedance measurements 10,000 s/sec/channel used for Pacemaker Artifact Detection	Pacemaker detection; Alarms; Lead off detection and transmission; Nurse call button; Generate a strip recording.	Pacemaker detection; Lead fail detection; LCD display; Battery Integrity transmitted; Alarm pause transmitted; Graph request transmitted; Power on/off.
Frequency Bands	915 Mhz or 2.45 Ghz	450 to 470 Mhz	174.050 to 215.950 MHz
Number of Channels	256 total, user selectable	266; not tunable	420 not tunable

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Mechanical Safety	Defibrillator protected when used with Mortara Instrument Patient Cable	Transmitter ECG input protected against 400 joules discharge into a 50 ohm load.	± 5000 VDC, 400 joules into 50 ohm load
Output Power	50 mV/m at 3 meters	10 mV/m at 3 meters	1.50 uV/m at 3 meters
Energy Used and/or Delivered	2 AA alkaline batteries (30 Hours)	9 Volt Battery (2.5 Days)	1.5 Volt Battery (2) (60 hrs)
Current Compatibility with Other Devices	Other Devices: ELI 100, ELI 200, Portrait, ELI-XR, X-Scribe Stress System, and ELI 100 STM	Other Devices: Patient Monitor/Holter Recorder Interface (Analog Output); ST Segment Analysis; HP M1401A Receiver Mainframe; HP M1402A Receiver Module; HP M1408A Antenna/Combiner	Other Devices: CD Telemetry-LAN Receiver Cabinet; CD Telemetry-LAN Antenna System; Centralscope
Where Used	Hospitals, Clinics	Hospitals, Clinics	Hospitals, Clinics
Standards	FCC Part 15 CAN/CSA 22.2 No. 601.1 UL 2601-1 IEC 601-1, 601-1-2, & 601-2-25 CE Marking for the 93/42/EEC Medical Device Directive	UL 544, CSA C22.2 No. 125M 1984 Risk Class 3, TUEV Certification to IEC 601-1, BSI BS5724: part 1:1979	FCC Part 15, Subpart E (Paragraph 15.241), UL 544 Listed. CE Marking for the 93/42/EEC Medical Device Directive
Electrical Safety	See Standards Above	Not Specified	Not Specified
Environmental	Operating Temp. Range: 10 to 32° C Storage Temp.: 0 to 45° C Humidity Operation: 20 to 80% Humidity Storage: 10 to 90% Atmospheric Pressure: .700-1060 millibars	Operating Temp. Range: 0 to 45° C Storage Temp.: -40 to 70° C Altitude: Operating up to 15,000 ft. Water Tight Seal (shower)	Operating Temp. Range: 0 to 50° C Storage Temp.: -20 to 60° C Altitude: Information Unavailable Water resistant; may submerge in water at a 1 ft. Depth for 1 hr w/out

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			damage.
Radio Channel Spacing	80 kHz (915 MHz) 320 kHz (2.15 GHz)	25 kHz	100 kHz
Modulation Type	Digital, frequency-shift keying	Digital, frequency-shift keying	PM/BPSK (Phase Modulated) digital transmission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Scott J. Pease
Manager of Quality Assurance
and Regulatory Affairs
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224

JAN - 8 1998

Re: K974149
Trade Name: Ambulatory X-12 Telemetry Module
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: October 31, 1997
Received: November 4, 1997

Dear Mr. Pease:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

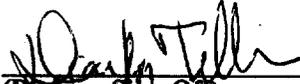
510(k) Number (if known): K974149

Device Name: Ambulatory X-12 Telemetry Module

Indications For Use: The device is intended to be used as a radiofrequency physiological signal transmitter and receiver to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another. The received signal is reconditioned by the device into its original format so that it can be displayed.

(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 K974149

Prescription Use X
(Per 21 CFR 801.109)

OR

~~Over-The-Counter Use~~ 