K060135

510(k): Device Summary

Submitter:

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Mortara Instrument, Inc.
7865 N. 86th Street
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Contact: Harlan Van Matre (see above)

Trade Name: Surveyor Telemetry Central Station
Common Name: Telemetry Central Station Monitor
Classification Name: The following Class II classifications appear to be applicable:

Device Name	Classification Name	CFR Section
Surveyor Central Station	Electrocardiograph	870.2340
	Arrhythmia detector and alarm	870.1025
	Monitor, ST Segment with Alarm	870.1025
	Patient Physiological Monitor, (with arrhythmia detection or alarms)	870.1025

Legally marketed devices to which S. E. is claimed

The Surveyor Telemetry Central Station is an evolution of a legally marketed Mortara predicate device.

- Mortara Model ST Central Station, (K922927)
- Datex-Ohmeda S/3 Telemetry Central System (K 000882)

Description:

The Surveyor Telemetry Central Station is a diagnostic tool intended to acquire, and provide real time ECG data of patients that require ECG monitoring during cardiovascular problematic situations. The cardiac data provided is reviewed, confirmed, and used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

The Surveyor Telemetry Central Station will be used for centralized ECG monitoring in a telemetry system consisting of three main components: the ambulatory ECG telemetry transmitters (X12 Ambulatory Transmitters), the receivers combined with an antenna network and the Central Station software application running on a PC.

The transmitter is attached to the patient and acquires a continuous 12-lead ECG signal. The signal is A/D converted and digital data is sent to the Central Station using wireless radiofrequency communication.

The antenna network receives the data sent by the transmitters. The network delivers the signal to the receivers installed in the Central Station PC. The receivers decode the data containing the ECG waveforms and status from the transmitters.

The Central Station retrieves the data from the receivers and performs arrhythmia and ST analysis on the signal. The result of the analysis can trigger an audiovisual alarm. The priority of each arrhythmia and ST alarm is defined in the alarm profile.

When used as a Telemetry Central Station, Surveyor Central Station is designed to work with ECG only or multi-parameter transmitters for ECG and SpO2. The Central Station can simultaneously retrieve, display and analyze ECG signals for up to 24 patients.

A single patient can be selected for reviewing data in the single patient view, which includes following displayed and printed data:

- All 12 real-time ECG leads.
- Current average and reference QRS complex with current ST levels for all leads
- The Central Station also stores waveforms, measurement data and alarms for 72 hours. The waveforms can be reviewed and printed

Intended Use:

The Surveyor Telemetry Central Station is designed to be used to monitor up to 24 adult patients during cardiovascular problematic situations, through ambulatory telemetry transmitter sources. When used as a Telemetry Central Station System, Surveyor Central is designed to work with ECG only or multi-parameter transmitters for ECG and SpO2. For each patients ECG waveforms, HR, ST values and other parameters (if available) will be displayed.

The Mortara Surveyor Central Telemetry System is intended for centralized ECG monitoring of hospital patients connected to telemetry transmitters such as the Mortara X12 Ambulatory Telemetry Transmitter (K974149), (presently marketed as the X12+), or other compatible telemetry transmitters. Patients are monitored through telemetry, when moving in a defined area, of a variable size depending on layout and thickness of walls. In order to guarantee a proper signal transmission in each different situation, an antenna network can be installed according to customer needs.

The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Indications for Use:

The Surveyor Central Telemetry System is intended for ECG analysis in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements

The Surveyor Central Telemetry System is indicated for use:

- ECG monitoring of adult patients in Coronary Care Units, Step-Down Units, Emergency Departments. It is not designed for use in highly invasive environments, such as an operating theatre.
- Centralized ECG monitoring through a telemetry network of adult patients. Continuous analysis is provided for all connected patients. It is not designed for use in highly invasive environments, such as an operating theatre.
- Evaluation of adult patients with symptoms suggesting arrhythmia. Detected arrhythmias create an audio-visual alarm according to the alarm profile.
- Chest Pain Evaluation.
- Evaluation of adult patients with pacemakers.
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Clinical and epidemiological research studies.

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K060135

Standard Organization No:
or
Standard Identification No:

IEC 60601-1
IEC 60601-1-1:2001
IEC 60601-1-4 A1:1999
ANSI/AAMI EC11-1991
ANSI/AAMI EC13:2002
(physiologic alarm)
ANSI/AAMI EC57 :1998
UL 2601-01

or
CDRH Internal Reference No:

Declaration of Conformity Elements:				
Any Adaptations Applied	yes		no	X
Any Requirements Not Applicable	yes	X	no	
Any Deviations Applied	yes		no	X
Any Differences in Device Tested and Finished Product	yes		no	X
*Is There a Third Party or Test Lab Involved	yes		no	X

Was there another standard used in the review of this submission? yes no X

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

Mr. Harlan L. Van Matre
Manager of Quality Assurance and Regulatory Affairs
Mortara Instruments, Incorporated
7865 North 86th Street
Milwaukee, Wisconsin 53224

Re: K060135
Trade/Device Name: Mortara Surveyor Telemetry Central Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: February 27, 2006
Received: April 27, 2006

Dear Mr. Van Matre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060135

Device Name: Mortara Surveyor Telemetry Central Station

Indications for Use:

The Surveyor Central Telemetry System is indicated for use:

- in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. Continuous analysis is provided for all patients. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements.
- centralized ECG monitoring through a telemetry network of adult patients in Coronary Care Units, Step-Down Units, Emergency Departments. It is not designed for use in highly invasive environments, such as an operating theatre.
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- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Clinical and epidemiological research studies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Cummins

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060135