K050951

p.1/3

JUL 1 9 2005

Section 16. 510(k) Summary

Section 16.a Date Summary Prepared

March 28, 2005

Section 16.b Company Information

Establishment:

Cybernet Medical.
727 Airport Blvd.
Ann Arbor MI 48108

Official Correspondent:

Eric Lichtenstein
Director
727 Airport Blvd.
Ann Arbor MI 48108
(734) 668-2567
(734) 668-8780 (fax)

Section 16.c Name of Device

Proprietary: MedStar System II

Common/Usual: MedStar

Classification: Radiofrequency physiological signal transmitter and receiver (§870.2910, DRG)

Section 16.d Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices and for the MedStar System II, as well as testing to accepted industry standards. In addition, bench testing was conducted to establish the MedStar System II's accuracy and performance to specification. The predicate devices are as follows:

Device Name	Manufacturer	510(k) Number
MedStar System	Cybernet Medical	K020534
HomMed Sentry IIIB-F Patient Monitor System	HomMed LLC	K040651
Viterion 100 TeleHealth Monitor	Viterion TeleHealthcare LLC	K030419

The MedStar System II's Intended Use, Indications for Use, feature set and performance specifications are similar to those of the above three predicate devices.

Section 16.e Device Description & Technological Characteristics

The MedStar Monitoring System II comprises the MedStar Unit and the associated Collection Server. The MedStar Unit is a portable, battery-operated unit for controlling the transmission of data from a range of compatible patient monitors or measurement devices to a remote monitoring center.

Data is transmitted via telephone lines to the associated data collection server at the remote site.

The MedStar Unit is contained in a small plastic enclosure with an LCD screen mounted into the top of the case. The case is made of a strong impact resistant plastic material. A User push button control is located adjacent to the display.

Four serial communication ports are located at the side of the unit for connection to the serial data ports of specific patient monitors.

Two standard phone jacks are also located at the side of the unit for connection to standard phone outlets.

Two recessed programming buttons are included on the opposite side of the enclosure to the phone jacks.

The Collection Server comprises a Personal Computer-type Processor Unit incorporating an additional electronics board to control phone line transmission to and from the MedStar Unit.

The MedStar System II accepts serial data from the following patient monitors or measurement devices:

Device	Clearance Information	Communication Protocols
Blood/Glucose Monitor Lifescan SureStep Blood/Glucose Monitor Lifescan OneTouch Ultra	K984261 K024194	Available Available
Weight Scale - A&D Medical UC-300 Weight Scale - A&D Medical UC321 Weight Scale - A&D Medical UC321PL	Scales Exempt from Premarket Notification, per 21CFR880.2720	Available Available Available
NIBP Monitor A&D Medical UA-767PC	K982481	Available
EKG Monitor King of Hearts Express King of Hearts Express 3X	 K920984 K920984	Not Applicable
Pulse Oximeter – Nonin PalmSat 2500	K002690	Available
Spirometer – PDS Healthcare KP+LFM	K013489	Available
Temperature Welch Allyn Suretemp Plus	K030580	Available
Prothrombin Time ITC ProTime Microcoagulation System	K010599	Available

Monitored/measured data is transferred from a patient monitor/measurement device, e.g. a Blood/Glucose Monitor or Weight Scale, via that unit's serial data port under the control of a serial port protocol. The data is then stored in the MedStar Unit prior to undergoing *Dual Tone Multiple Frequency,* DTMF, encoding to facilitate phone line transmission to a remote site, such as a Disease Management Center.

A Collection Server comprising a Personal Computer with an additional communications board, receives and decodes the transmitted data and stores the data locally for subsequent transfer to a Hospital Information System for review by a healthcare professional.

Section 16.f Intended Use

The MedStar System II is intended to transfer patient physiological data from a range of patient monitors to a remote station, such as a Disease Management Center, for subsequent transfer by a Hospital Information System for review by a healthcare professional. The MedStar System II is intended for use with any patient requiring Out-of-Hospital monitoring. The MedStar System II is not used directly with a patient.

The MedStar Unit is intended for Out-of-Hospital Use. The associated Collection Server is intended for use in a Disease Management Center, Hospital or Hospital-Type facility, Medical Clinic or Physician's Office. The MedStar System II is intended for sale by or on the order of a physician only.

The intended use, patient population and environment of use are the **same** or **similar** to the predicate devices, the Cybernet Medical MedStar System (K020534), the HomMed LLC HomMed Sentry IIIB-F Patient Monitor System (K040651) and the Viterion TeleHealthcare LLC Viterion 100 TeleHealth Monitor (K030419).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Cybernet Systems Corp.
c/o Mr. Eric Lichtenstein
Regulatory Affairs
727 Airport Blvd.
Ann Arbor, MI 48108-1639

Re: K050951
Trade Name: MedStar System II
Regulation Number: 21 CFR 870.2920
Regulation Name: Electrocardiograph Telephone Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 17, 2005
Received: June 27, 2005

Dear Mr. Lichtenstein:

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 may be obtained 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):K050951

Device Name: MedStar System II

Indications For Use:

The MedStar System is indicated for Out-of-Hospital Use with any patient requiring Out-of-Hospital monitoring.

The associated Collection Server is intended for use in a Disease Management Center, Hospital or Hospital -Type facility, Medical Clinic or Physician's Office.

Eric Lichtenstein
Regulatory Affairs, Cybernet Medical

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050951