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Section 16. SECTION 16. 510(k) SUMMARY.

FEB 11 2003

Section 16.a Date Summary Prepared

February 15, 2002

Section 16.b Company Information

Establishment:

Cybernet Medical.
727 Airport Blvd.
Ann Arbor MI 48108

Official Correspondent:

David A. C. Green
Regulatory Affairs Consultant
for Cybernet Medical.
1460 Golfcrest Place
Vista, CA 92083
(760) 599 9661
(760) 599-9661 (fax)

Section 16.c Name of Device

Proprietary:	MedStar System
Common/Usual:	MedStar
Classification:	Telephone Electrocardiograph transmitter and receiver (§870.2920/74DXH)

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, as well as testing to accepted industry standards. In addition, bench testing was conducted to establish the MedStar System's accuracy and performance to specification. The predicate devices are as follows:

- Home Care Monitoring System, AvidCare Corp., K010029
- Model EHC 400 Desktop Patient Station, Cybercare Technologies Inc., K003257
- PaceArt Central Station CPTS 86-12, PaceArt Inc., K915632

Section 16.e Device Description & Technological Characteristics

The MedStar Monitoring System 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.

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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 accepts serial data from the following patient monitors or measurement devices:

Device	Communication Protocol
Blood/Glucose Monitor Lifescan SureStep	Available
Weight Scale - A&D Medical UC-300 Weight Scale - A&D Medical UC-321	Available Available
NIBP Monitor - A&D Medical UA-767PC	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 by a Hospital Information System for review by a healthcare professional.

In addition to transferring encoded data from the three measurement devices described above, EKG data may also be transferred directly from an EKG Monitor to the Collection Server, via phone line, using an EKG Monitor's standard audio data output.

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Section 16.f Intended Use

The MedStar System 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 is intended for use with any patient requiring Out-of-Hospital monitoring. The MedStar System 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 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 Avid Care Corporation Home Care Monitoring System, K010029, the Cybercare Technologies Model EHC 400 Desktop Patient Station, K003257 and the PaceArt Central Station CPTS 86-12, K915632.

Section 16.g Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Cybernet Medical believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

Eric D. Lichtenstein
Product Development Manager
Cybernet Medical.

David A. C. Green
Regulatory Affairs Consultant
for Cybernet Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2003

Cybernet Medical
c/o Mr. David A.C. Green
Regulatory Consultant
BBP Consultants Inc.
1460 Golfcrest Place
Vista, CA 92083

Re: K020534
Trade Name: MedStar System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: November 29, 2002
Received: December 2, 2002

Dear Mr. Green:

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

2.g INDICATIONS FOR USE STATEMENT

Applicant: Cybernet Medical.

510(k) Number: K020534

Device Name: MedStar System

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.

Prescription Use: Yes (Per 21 CFR 801.109).

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K020534

Prescription Use X or OTC Use _____