K040799

AUG 18 2004

510(k) Summary

HomMed Genesis Patient Monitor System

Date: March 25, 2004

Submitter: HomMed, LLC
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Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
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Houston, TX 77008
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Trade Name: HomMed Genesis Patient Monitor System with Options

Common Name: Patient Vital Signs Monitor with Options

Classification Name: Oximeter
Classification Number: DQA

Predicate Device(s): HomMed Sentry III Patient Monitor System with Card Reader

Device Description: The HomMed Genesis Patient Monitor System with Options (HomMed Genesis) is a portable patient vital signs monitoring system. The system measures pulse oximetry (optional), noninvasive blood pressure, pulse rate, and weight. HomMed Genesis will have four serial ports available for external options. The Genesis acquires the patient vital signs data and displays it. The data can also be transmitted via the communication system through the Skytel or PageNet Pager Network to a central station for storage with retrospective display and analysis.

Intended Use: Genesis is a system designed to monitor patient vital signs at home and/or in healthcare facilities. Vital signs include pulse oximetry (optional), noninvasive blood pressure, pulse rate, and weight. Vital signs data is transmitted via modem to a central viewing station for display, analysis and monitoring by healthcare professionals. All patient data is collected, stored, forwarded and displayed in a retrospective manner, and is not intended to provide real-time critical care monitoring of patients, nor any local alarms or alerts of patient status. Genesis is intended for use with adult and pediatric patients over twelve years of age. The card reader

functionality allows a single patient to use multiple monitors or multiple patients to use a single monitor.

Technology: The HomMed Genesis employs the same technologies as the predicate device, HomMed Sentry III Patient Monitor System with Card Reader.

Test Summary: The Genesis monitor complies with the following voluntary standards:

- EN 60601-1 Medical Electrical Safety
- IEC 601-1-2 EMC Compliance
- ISO 10993-5,10-11 Biocompatibility

Conclusion: It is the HomMed position that the results of these measures demonstrate HomMed Genesis is as safe, as effective and performs as well as the legally marketed predicate device, HomMed Sentry III Patient Monitor System with Card Reader.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2004

HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K040799
Trade Name: HomMed Genesis Patient Monitor System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 29, 2004
Received: July 30, 2004

Dear Dr. Morgan:

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. for
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: HomMed Genesis Patient Monitor with Options

Indications For Use:

The HomMed Genesis Patient Monitor with Options is a system designed to monitor patient vital signs at home and/or in healthcare facilities. Vital signs include pulse oximetry (optional), noninvasive blood pressure, pulse rate, and weight. Data from optional commercial stand-alone products including glucose meter, spirometer, and prothrombin time can be exported via the Genesis communication module. Vital signs data is transmitted via modem to a central viewing station for display, analysis and monitoring by healthcare professionals. All patient data is collected, stored, forwarded and displayed in a retrospective manner, and is not intended to provide real-time critical care monitoring of patients, nor any local alarms or alerts of patient status.

HomMed Genesis is intended for use with adult and pediatric patients over twelve years of age. The card reader functionality of HomMed Genesis allows a single patient to use multiple monitors or multiple patients to use a single monitor.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 K040799