K003180

JUN 2 8 2001

510(k) Summary for HomMed Observer, Model I

Submitter:	HomMed, LLC
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Prepared:	September 21, 2000
Proprietary Name:	HomMed Observer, Model I
Common/Classification Name:	Physiologic Data Display and Analysis System
Predicate Device:	HomMed Sentry
New Device Description:	HomMed Observer

Intended Use:
The HomMed Observer intended use is to retrospectively receive, display, evaluate, analyze and store certain monitored physiological parameters of patients when this data is acquired within healthcare and home environments. The Observer is the accessory device used by the healthcare professional to display and evaluate the monitored patient data from the HomMed Sentry, and the healthcare professional is responsible for the interpretation of the monitored data made available by the Observer. The data received from the Sentry and displayed by the Observer will be utilized by healthcare professionals, (including physicians and/or physician supervised nurses), to retrospectively view patient physiological data. Physiological data, system alerts and patient data analysis will be available to the health care provider from Observer. The Observer is a retrospective data view and analysis system. The Observer is not intended for emergency use or real-time monitoring of data received from the Sentry.

Performance Data:
The HomMed Observer is a software system that operates on a commercially available PC system with the minimum performance specifications consistent with typical PC hardware and equipment specifications. The HomMed Observer is a software system that is an accessory to the HomMed Sentry which is the predicate

device. The software validation results demonstrated that the HomMed Observer System was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

Compliance to Standards and Regulations:

Safety

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K003180
Trade Name: HomMed Observer, Model I
Regulation Number: 870.1130
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: March 28, 2001
Received: March 30, 2001

Dear Dr. Morgan:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4646. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003180

Device Name: HomMed Observer

Indications for Use

The HomMed Observer is intended to be used to retrospectively receive, display, evaluate, analyze and store certain monitored physiological parameters of patients within healthcare and home environments. The physiologic patient parameters available for retrospective display and evaluation include NIBP, pulse rate, SpO2, temperature and weight. The Observer will be the device used by the healthcare professional to display and evaluate the monitored patient data, and the healthcare professional is responsible for the interpretation of the monitored data made available by the Observer. The Observer data will be utilized by healthcare professionals including physicians and/or physician supervised nurses. Physiological data, system alerts and patient data analysis will be available to the health care provider from Observer as a retrospective data monitor system. Observer is not intended for emergency use or real-time monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ Only ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003180