

MAR 15 2000

K993938

HomMed LLC

February 15, 2000

510(k) Summary for HomMed Model Sentry

Submitter: HomMed LLC
Address: 19275 West Capital Drive, Suite 200
Brookfield, Wisconsin 53045

Telephone: (414) 783-5440

Contact: Herschel Peddicord, President

Prepared: February 15, 2000

Proprietary Name: HomMed Model Sentry

Common/Classification Name: Noninvasive blood pressure measurement system

Predicate Devices: BCI Mini-Torr Plus (model 6004) with new electronic thermometer option; and, BCI 6004 NIBP monitor Welch Allyn 678 SureTemp Thermometer

New Device Description:

HomMed Model Sentry patient monitor provides a manually initiated sequence of automatic patient measurements. The Sentry patient monitor consists of a small tabletop NIBP monitor with a desktop charger. Features include an NIBP cuff hose connection, an SpO₂ sensor interface, a oral temperature probe interface and holder, display of patient systolic, diastolic, and mean arterial pressure, interval timer, SpO₂, pulse rate, pulse strength, temperature via an LED display.

The HomMed Model Sentry is the existing presently marketed BCI Mini-Torr Plus noninvasive blood pressure (NIBP) monitor with oximeter and electronic thermometer options with certain defeatures implemented via software toggle off/on function controls. The BCI Mini-Torr Plus monitor has a FDA 510(k) approval, Number K983796.

Intended Use:

The HomMed Model Sentry monitor is a portable noninvasive blood pressure (NIBP) monitor for spot checking of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures, pulse rate using an oximeter and oral temperature via an electronic thermometer. The device will provide fast, reliable NIBP measurements on patients ranging from children (pediatrics) to adults when using the appropriate blood pressure cuff provided. The oximetry works with Model Sentry oximetry probes provided by HomMed, providing SpO2 and pulse rate on all patients from pediatric to adult. The electronic thermometry requires use of the Welch Allyn oral thermometry probe and probe covers. It will provide oral temperature information only. The device is intended for use in clinical environments by health care professionals and in home use by patients as prescribed by or on orders by a physician.

Performance Data:

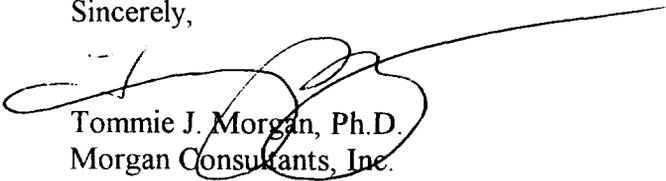
The HomMed Model Sentry utilizes the technology in the BCI 6004 monitor and performs within the environments for which Sentry is marketed. BCI has performed in accordance with the guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the Sentry 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.

Since the HomMed Model Sentry is the BCI 6004, which has met and continues to meet the applicable FDA requirements, it was not necessary to do additional performance testing. The performance of the Sentry and the BCI Model 6004 remains unchanged.

The HomMed Model Sentry performance is the BCI 6004 performance and no additional or different testing has been done on the HomMed Model Sentry patient monitor. Thus it is the HomMed position that the Sentry performs as well as the legally marketed predicate device, BCI Model 6004.

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

Sincerely,



Tommie J. Morgan, Ph.D.
Morgan Consultants, Inc.

On Behalf of:
Herschel Peddicord, President
HomMed LLC



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

Ms. Herschel Peddicord
Hommed LLC
19275 West Capitol Drive, Suite 200
Brookfield, WI 53045

Re: K993938
The Hommed Sentry, Model 1 Sentry
Regulatory Class: II (two)
Product Code: DXN
Dated: January 20, 2000
Received: January 21, 2000

Dear Ms. Peddicord:

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 (Pre-market 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.

Page 2 - Ms. Herschel Peddicord

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) 594-4648. 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" (21 CFR 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993938

Device Name: HomMed Model Sentry

Indications for Use:

The HomMed Model Sentry patient monitor system is for spot checking of adult or pediatric patient's systolic, diastolic and mean arterial (MAP) blood pressures, pulse rate, SpO₂ oximetry and oral temperature. The device will provide fast, reliable NIBP measurements on patients when using the appropriate blood pressure cuff. The oximetry function operates with all OEM (BCI) oximetry sensors, providing SpO₂ and pulse rate on all patients from pediatric to adult patients. The electronic thermometry is intended for oral temperature measurements and is only compatible with the Welch Allyn thermometry probes and probe covers. The device is intended for use in clinical environments by health care providers and for home use by patients with retrospective review by health care providers.

Federal law restricts this device to sale by or on the order of a physician.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993938

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the Counter Use

(Optional Format 1-26-96)