Submitter

Zoe Medical Incorporated
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Contact Name: Stephen Staats
Contact Title: Quality System Manager

Date this Summary was Prepared: December 11, 2003

Trade Name

Well@Home System

Common Name

Noninvasive Blood Pressure Measurement System

Classification Name

Noninvasive Blood Pressure Measurement System (per 21 CFR 870.1130)

Predicate Devices

Overall Predicate Device:

HealthTech HANC (Home Assisted Nursing Care) Network 510(k) number K952979

Vital Signs Predicate Devices:

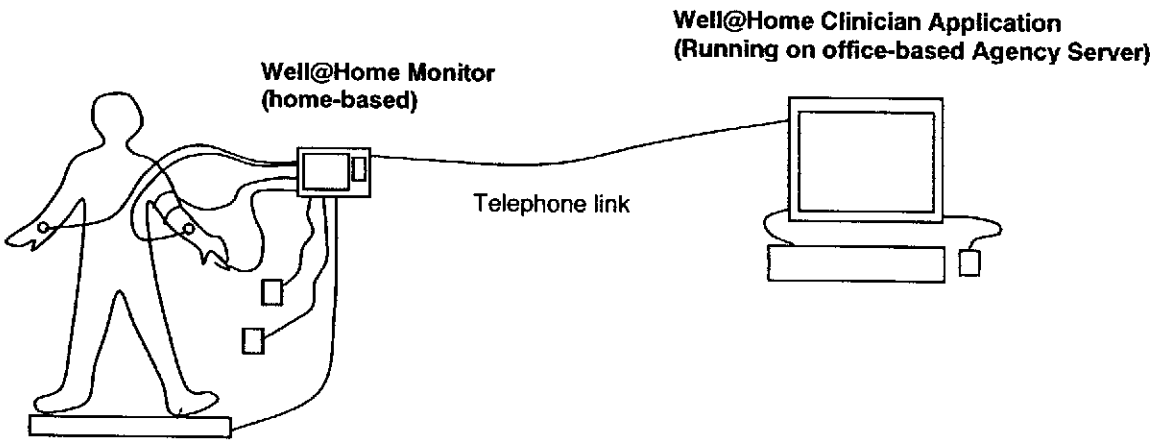
Zoe Medical Nightingale Monitoring System 510(k) number K001775

(for measuring noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, heart rate, and ECG)

Lifescan One Touch Ultra 510(k) number K024194

(for measuring blood glucose level)

Device Description



The Well@Home System consists of the home-based "Well@Home Monitor" and the office-based "Well@Home Clinician Application". Using the Well@Home System, clinicians can monitor their patients at home or in another remote health care facility. The use model is "daily checkups", rather than continuous monitoring.

The Well@Home Monitor collects vital signs and symptom information on a periodic basis via a patient-friendly user interface. The user interface guides the patient through a schedule of activities using voice prompts, instructional diagrams and large, easy-to-read buttons. The scheduled activities can include reminders to take medications or to take vital signs measurements. The schedule for these activities can be customized by the clinician according to the patient's medical condition. The user interface also provides opportunities for the patient to report symptoms at any time, and to review training content related to managing the patient's illness.

The Well@Home monitor measures noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, heart rate, and ECG. The Well@Home Monitor is designed to interface to Other Medical Devices (OMD's) for the purpose of gathering physiological data from those devices. The interface is through the monitor's three OMD serial ports. These serial ports are electrically isolated from each other and from the monitor's own physiological front-end. The list of supported OMD's is as follows:

- Fairbanks Digital Scale (private labeled and device listed as a Zoe Medical accessory)
- Lifescan One Touch Ultra Blood Glucose Meter (or compatible BGM from Lifescan)

The OMD interface mechanism is designed to be expandable. Future OMD's may include a Spirometer or a PT/INR measurement device.

The Well@Home Monitor transmits the gathered information to a clinician over the patient's existing telephone line. This information is received and stored by the Well@Home Clinician Application.

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The Well@Home Clinician Application is essentially a patient data management and record keeping program that includes an interface to the Well@Home Monitor. The Well@Home Clinician Application stores information that is gathered from multiple Well@Home Monitors and allows a clinician to review a given patient's information. It also allows the clinician to make adjustments to a patient's schedule of activities as needed. These adjustments are sent back to the patient's Well@Home Monitor over the same telephone link.

The Well@Home Clinician Application software was developed by Patient Care Technologies (PtCT) of Atlanta, Georgia, and is designed to run on standard Windows-based PC's. These PC's are typically installed at the office of a home care agency, and are referred to in this 510(k) as "Agency Servers". The Agency Servers may run other information management software developed by PtCT that is not part of the Well@Home System. The Well@Home System is product-branded to tie into PtCT's information management software product line.

Because of the remote-monitoring and spot check nature of the Well@Home System, there are no real-time "alarms" as in a hospital-style monitor. Rather, the clinician defines "alerts" that are to be generated (e.g., when a vital sign parameter exceeds set limits or when a particular symptom is reported). These alerts are part of the information package that is sent from the Well@Home Monitor to the Well@Home Clinician Application. The alerts are then visually highlighted when the clinician reviews the patient's information.

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K040012

Intended Use

The Well@Home System is intended to be used as a clinical tool for remotely monitoring a patient's health status at home or in another healthcare facility. The system is intended to guide patients through a set of scheduled activities whereby medical data (vital signs, symptoms, and medication compliance) is collected. The system is intended to transfer the collected data to a remote site where it is stored and reviewed by a clinician. The system is also intended to allow the clinician to modify the patient's scheduled activities in response to the collected medical data or other information available to the clinician. The intent is to provide clinicians caring for patients outside the hospital with a means for keeping track of how the patients are doing without requiring the patients to come in for a checkup or requiring the clinicians to go to the patients.

The Well@Home System is indicated for use for patients who need home-based health care from professional clinicians. The system provides benefits for patients who need periodic remote monitoring of their vital signs (such as noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, weight, blood glucose level, heart rate, or ECG) or self-reported symptoms, who need reminders to take prescribed medications, or who need training about how to manage their illness.

The Well@Home System is not an emergency response system. The device labeling advises patients to contact their caregiver, nurse, or doctor, or to call 911, or to go in to the Emergency Room, whenever they feel the need to do so. The device labeling refers patients to printed information they receive from their clinicians as their primary source of information. Furthermore, the Well@Home System does not analyze patient information nor does it offer medical advice.

The initial target customers for the Well@Home System are Home Health Care Providers, who will place the product in their patient's home. Target patient conditions include CHF, diabetes, COPD, and hypertension. While the Well@Home System is intended for use in adult and pediatric patients, the user interface is tailored for an adult operator. The Well@Home System is not intended for use on neonatal patients.

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Technological Characteristics Compared to Predicate Devices

The Well@Home System incorporates technological characteristics that are very similar to three devices that have received 510(k) clearance.

For purposes of evaluating overall substantial equivalence, technological characteristics of the system related to the functions of scheduling patient activities, providing training information, collecting vital sign and symptom data, transferring data to a remote nurse, and allowing clinicians to modify patient scheduled activities, are compared to the HealthTech HANC (Home Assisted Nursing Care) Network.

Technological characteristics related to the measurement of physiological vital signs (noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, heart rate, and ECG) are compared to the Zoe Medical Nightingale PPM (Personal Patient Monitor), part of the Nightingale Monitoring System.

Technological characteristics related to measuring blood glucose level are compared to the Lifescan One Touch Ultra.

Well@Home System in Comparison to the HANC (Home Assisted Nursing Care) Network

The Well@Home System and the HANC Network both have the same general intended use. Both systems provide means for remote monitoring of a patient's health status at home or in another healthcare facility.

Both systems have the overall function of collecting medical data about a patient (vital signs and symptoms) and transferring the data to a remote site for storage and review purposes. The list of vital signs collected by both systems is similar: noninvasive blood pressure, temperature, oxygen saturation, pulse rate, respiration, and ECG.

Both systems employ the concept of connecting previously 510(k) cleared Original Equipment Manufacturer (OEM) components to measure certain vital signs parameters.

Both systems have similar features such as managing scheduled activities, medication reminders, coaching screens, and symptom reporting.

Both systems have similar principles of operation, combining a programmable device placed with the patient together with a device at the clinician's office that interacts with the patient device via a remote communications link.

Both systems have similar technological characteristics, combining touch screens, voice prompts, modems and PC technology.

The differences between the Well@Home System and the HANC Network are minor, and consist mainly of auxiliary, optional functions that the Well@Home System does not implement, such a connecting to an electronic stethoscope and to a video camera. These functions are not central or even required for the intended use of either system, and thus do not diminish the claim of substantial equivalence.

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For all of the above-stated reasons, the Well@Home System is substantially equivalent to the HANC Network. Internal engineering tests verified the performance of the Well@Home System in all functions that are similar to those that are performed by the HANC Network. The Well@Home System performed according to its functional requirements and passed all of these tests.

Well@Home System in Comparison to the Nightingale PPM (For Vital Signs Measurement)

Both the Well@Home Monitor and the previously 510(k) cleared Nightingale PPM are designed and manufactured by Zoe Medical. The Well@Home monitor contains the same signal processing front-end hardware design as the Nightingale PPM, acquires the same physiological parameters, and uses the same software algorithms. For these reasons, bench tests using simulators were used to verify the performance of the Well@Home Monitor. These tests showed that on all physiological vital signs measured by the Nightingale PPM (noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, heart rate, and ECG), the performance of the Well@Home Monitor was substantially equivalent to the Nightingale PPM.

Well@Home System in Comparison to the One Touch Ultra (For Vital Signs Measurement)

The One Touch Ultra blood glucose meter (BGM) is a previously 510(k) cleared device that provides a measurement of the patient's blood glucose level. The manufacturer (Lifescan) provides a custom interface cable that allows remote access to the BGM from devices such as the Well@Home Monitor. In this capacity (regarding blood glucose level measurements), the Well@Home Monitor functions as information transfer technology. The performance of the BGM is no different when it is connected to the Well@Home Monitor as when it functions as a standalone device. Internal engineering tests confirmed that the measurement results provided by the BGM were correctly collected and displayed by the Well@Home System.

Conclusions

Based on technological comparisons and performance testing results, in its overall intended use, functioning, safety and efficacy, the Well@Home System is substantially equivalent to the HealthTech HANC Network.

Based on technological comparisons and performance testing results, the vital signs measurement function of the Well@Home System is substantially equivalent to the vital signs measurement function of the Zoe Medical Nightingale PPM for measuring noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, heart rate, and ECG.

Based on technological comparisons and performance testing results, the vital signs measurement function of the Well@Home System is substantially equivalent to the vital signs measurement function of the Lifescan One Touch Ultra for measuring blood glucose level.

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Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Zoe Medical, Incorporated
c/o Mr. Stephen Staats
Quality System Manager
460 Boston Street
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Re: K040012
Trade Name: Well@Home System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: December 30, 2003
Received: January 05, 2004

Dear Mr. Staats:

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) 594-4648. 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 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): K040012

Device Name: Well@Home System

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The Well@Home System is indicated for use for patients who need home-based health care from professional clinicians. The system provides benefits for patients who need periodic remote monitoring of their vital signs (such as noninvasive blood pressure, oxygen saturation, pulse rate, temperature, respiration rate, weight, blood glucose level, heart rate, or ECG) or self-reported symptoms, who need reminders to take prescribed medications, or who need training about how to manage their illness.

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

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040012