K060194

MARCH HEALTHCARE
A March Networks Company

FEB 13 2006

510(k) Summary of Safety and Effectiveness

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Date: November 4, 2005

Trade Name: March Healthcare HMK

Common Name: Health Monitoring Kit

Classification Name: Non-Invasive Blood Pressure Measurement System

Product Code: DXN

Legally Marketed Devices: The March Healthcare HMK is substantially equivalent to the legally marketed devices listed in the chart below.

LEGALLY MARKETED DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
CLINICAL VITAL SIGNS MONITOR, MODEL #52STP-E1 (52000)	Welch Allyn Inc	Class II/DXN	K951193
E-Scope Electronic Stethoscope Model 7187-120	Cardionics	Class II/DQD	K961301

The new March Healthcare HMK is substantially equivalent to the legally marketed devices listed based on the following rationale:

- ✓ Same indications for use: for non-invasive monitoring of blood pressure, heart rate, functional oxygen saturation, and pulse rate of adult and pediatric patients in various health environments.

- ✓ Similar key design technical characteristics- The HMK, like the Welch Allyn monitor, contains comparable modular-based blood pressure monitor and SpO2 components. These OEM modules are currently in use in devices that have already been FDA approved for market. The HMK incorporates Nonin's Ipod or Xpod pulse oximetry technology and CAS Medical's NE NIBP module. In addition, the HMK incorporates Cardionics' networked electronic stethoscope technology into its design.

- ✓ Same/similar components for measuring the vital signs of patient.

- ✓ Similar size (hand held), weight, power source, and performance.

Description:

The March Healthcare Health Monitoring Kit (HMK) is a portable medical device equipped with a built-in blood pressure monitor, pulse oximeter, and electronic stethoscope intended for spot-checking the basic vital signs of pediatric patients aged three and older and adult patients under the care of a physician in both clinical and home environments. The HMK can be used as a stand-alone unit or it can be connected to a host using a standard Bluetooth® wireless interface or wired universal serial bus (USB) interface to support remote control of the HMK and audio and data transmission in telehealth applications.

In both stand-alone and remote telehealth applications, the user can spot-check the following vital signs with the blood pressure monitor and pulse oximeter: heart rate and systolic and diastolic blood pressure, and functional blood oxygen saturation and pulse rate. In remote telehealth applications when the HMK is interfaced with a host, the electronic stethoscope transmits heart and lung sounds via the host to a health care professional at a remote computer. The data from the HMK can be viewed in one of two ways: on the built-in HMK liquid crystal display (LCD) or from a remote computer connected to a host.

The HMK blood pressure monitor uses the non-invasive, oscillometric, step-wise deflation method to measure heart rate and systolic and diastolic blood pressure. The non-invasive pulse oximeter measures functional blood oxygen saturation and pulse rate using a photodetector and a red and infrared light source to measure the absorption of red and infrared (IR) light passed through the tissue and arterial hemoglobin. The electronic stethoscope uses a microphone within the chestpiece, behind a diaphragm. The microphone converts the sound in the chestpiece to an electronic signal for amplification and transmission to a health care professional at a remote computer via the host.

The HMK does not store physiological data in memory. When using the HMK as a stand-alone unit, the user must manually record the results displayed on the LCD. However, when the HMK is interfaced with a host, the host may store the audio and physiological data in a database for remote access by authorized clinicians.

The HMK is powered with either a Sealed Lead Acid (SLA) battery or a Medical Grade IEC 60601-1 compliant AC adapter. The AC adapter is also used to charge the SLA battery.

The HMK has only two external inputs: AC adapter input and universal serial bus (USB) input. The user connects the AC adapter to the DC power plug socket when the battery needs charging. In addition, the user can connect the HMK to the host using the Type B USB input as a wired alternative to the wireless Bluetooth interface.

The HMK is for sale by or on the order of a physician.

Intended for Use:

The March Healthcare Health Monitoring Kit (HMK) is a non-invasive, spot-measuring device intended to measure heart rate and systolic and diastolic blood pressure using the oscillometric method; functional oxygen saturation levels; pulse rate; and heart and lung sounds of both pediatric patients aged three years and older and adult patients under the care of a physician in either clinical or home enviroments.

Technological Comparison to the Legally Marketed Devices:

Technologically, the March Healthcare HMK is substantially equivalent to the legally marketed devices listed above. The risks, safety and effectiveness, and benefits of the March Healthcare HMK are also comparable. The Table of Comparison in Section 4 will provide additional information illustrating that the new March Healthcare HMK is substantially equivalent to the Welch Allyn 52000 and the Cardionics E-Scope Stethoscope.

To highlight:

- The Non-Invasive Blood Pressure measurement specifications and performance are equivalent to the Welch Allyn 52000 Vital Signs Monitor (K951193). The HMK and the Welch Allyn 52000 Vital Signs Monitor use a CAS Medical OEM NIBP module that is similar in design.

- The HMK SpO2 measurement and performance specifications are equivalent to the Welch Allyn 52000 Vital Signs Monitor (K951193) because both units use Nonin OEM pulse oximetry technology.

- The heart and lung sound specifications and performance are derived from the Cardionics stethoscope (K961301). The networked electronic stethoscope is an added feature on the HMK that is not available on the Welch Allyn 52000. However, the stethoscope has been approved for market by the FDA to be incorporated into systems like the HMK; consequently, the inclusion of the FDA-approved stethoscope technology raises no new issues of safety and effectiveness and does not affect a substantial equivalence determination.

Materials and Biocompatibility:

The blood pressure monitor, pulse oximeter and electronic stethoscope modules are encased in an UL-approved acrylonitrile-butadiene-styrene (ABS) injection molded carrying case.

The following components contact the patient:

- **A & D Medical LifeSource Pressure Cuffs:** The pressure cuff is made from cloth material (6-nylon) and the cuff hose is made from latex-free PVC plastic.
- **Nonin Pulse Oximeters:** All oximeter sensors are constructed using materials that have been previously validated by Nonin for biocompatibility per ISO 10993.
- **Cardionics Stethoscope:** The stethoscope chest piece is made from steel.

These patient contacting materials have a history of biocompatibility with respect to patient contact. These materials contact the patient in the same locations for less or the same amount of time. Moreover, March Healthcare Corporation has not modified these materials in any way. A&D Medical, Nonin, and Cardionics have tested all patient contacting equipment and accessories for biocompatibility, and these manufacturers have obtained adequate biocompatibility results. For these reasons, March Healthcare Corporation believes that no further biocompatibility testing is required.

Summary of Performance Testing:

The March Healthcare HMK was tested for comformance to the design specifications in accordance to the HMK Validation Test Plan, included with the submission, using production equivalent units prior to release to market. The HMK passed all tests and demonstrates the functionality indicated in the design specifications for the unit.

A risk analysis identifying potential hazards and documenting mitigations of the hazards has been developed and applied as part of the March Healthcare Corporation product development cycle. The risk analysis is based on ISO14971 - Risk Analysis for Medical Devices.

Comparative testing between the March Healthcare Health Monitoring Kit and the Welch Allyn 52000 Vital Signs Monitor (K951193) was performed to validate the functional performance of the March Healthcare HMK. In particular, CAS NE NIBP and Nonin SpO2 performance tests were performed to show substantial equivalence to the Welch Allyn 52000 VSM. Comparative testing was performed between the HMK and the E-Scope Electronic Stethoscope Model 7187-120 for similar frequency response. The comparison testing was performed with each vital signs measurement device and demonstrated that the HMK and the Welch Allyn 52000 Vital Signs Monitor and the HMK and the Cardionics E-Scope perform equivalently.

The HMK has been subjected to performance testing to applicable safety, electrical, mechanical, EMC standards, and environmental standards. All specifications were met.

Conclusion:

The March Healthcare Health Monitoring Kit (HMK) is safe and effective, complies with the appropriate medical standards, and is substantially equivalent in performance, design and intended use to the legally marketed devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

March Healthcare Corporation
c/o Ms. Laura Danielson
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K060194
Trade Name: Health Monitoring Kit (HMK)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 24, 2006
Received: January 25, 2006

Dear Ms. Danielson:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

B Zimmerman for

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 K060194 (To be assigned)

Device Name:	Health Monitoring Kit (HMK)
Indications for Use:	The Health Monitoring Kit (HMK) is a non-invasive, spot-measuring device used to measure blood pressure, heart rate, oxygen saturation levels, pulse rate, and heart and lung sounds.
Target Population:	Pediatric patients over the age of three and adult patients who are under the care of a health care professional.
Environment of Use:	For use in clinical environments by health care professionals and/or in home environments by patients under the care of a physician.

Prescription Use: ✓ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 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 K060194