K101445
p1/3

5. 510(k) Summary

Date: February 15, 2010

Submitted By:
Welch Allyn, Inc.
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JUN - 8 2010

Common Name: Cardiovascular Monitoring Devices

Trade Name: Vital Signs Monitor – VSM 6000 Series

Classification: 21 CFR 870.2300; Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

Predicate Device: The predicate devices for these vital signs monitors are:

- Welch Allyn VSM- Vital Signs Monitor (VSM 300) 53000 series cleared through FDA 510(k) no. K063419
- Welch Allyn Non-invasive Blood Pressure (NIBP) Device cleared through FDA 510(k) no. K093907
- Welch Allyn Spot Ultra Vital Signs Device cleared through FDA 510(k) no. K040490

Description: The Welch Allyn VSM 6000 series is designed to provide a scalable, modular system that could be configured to address the needs for vitals signs spot check and monitoring, by using interchangeable components

The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2) and body temperature of neonatal, pediatric and adult patients.

The overall device has an enclosure constructed of engineering plastics with internal steel members for strengthening. A silicone light bar is prominent in a carry handle on the top of the device and illuminates for different alarm conditions. A power button is located on the side of the device. A LCD with a touch screen is prominent on the front of the device and provides the primary interface for the user to interact with the device. Internal and external communications is primarily by USB. External host USB connections for accessories are tool accessible. A user accessible client USB connection for data transfer is on the side of the device. A connection to an internal relay for use with nurse call systems is provided on the side of the device. The device contains an internal AC power supply for operating the device and charging the internal Lithium Ion battery.

Noninvasive blood pressure is determined using the oscillometric method and is acquired during cuff inflation or cuff deflation. The blood pressure measurement capability is contained in an enclosed sensor module internal to the device that provides a hose connection out the side of the device. This device implements a previously cleared Welch Allyn NIBP module and cuffs.

Noninvasive functional oxygen saturation of arteriolar hemoglobin is determined through the absorption rate of transmitted or reflected light from a sensor applied to different body sites. This capability is contained in an enclosed sensor module that provides a sensor connection to device. This device implements sensor technology from previously cleared Nellcor and Masimo devices including circuit boards and sensors for different body sites.

Body temperature is determined by a thermister based temperature probes that can be used in oral, axillary, rectal body sites. Measurement is made through a predictive measurement as the probe temperature increases towards equilibrium with the body site and by streaming temperature data from the probe to the display. Contact of the stainless steel probe is separated from the patient by use of disposable plastic probe cover. This capability is contained in a sensor module internal to the device that provides a temperature probe connection out the front of the device. This device implements technology and probes from a previously cleared Welch Allyn device.

Intended Use: The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. This product is available for sale only upon the order of a physician or licensed health care professional.

Contraindication for Use:

This system is not intended to be used:

- on patients connected to heart/lung machines
- on patients being transported outside a healthcare facility
- near an MRI machine
- in a hyperbaric chamber
- near flammable anesthetics
- near electro-cauterization devices

Technological Characteristics:

The Welch Allyn VSM 6000 Series Device utilizes an Oscillometric Blood Pressure Measurement (BP) algorithm, Thermometer and SpO2 algorithm that is equivalent to the algorithm used in the Welch Allyn NIBP, Spot

Ultra Vital Signs and Welch Allyn VSM 53000 (VSM 300 series). The Welch Allyn VSM 6000 Series Device is powered from AC power and Battery power. It uses the same operating principle and incorporates the same basic material as the previously cleared predicate devices. The subject device has the same technological characteristics as the predicate devices.

Non-clinical performance data:

The subject device was also tested to evaluate its safety and effectiveness based on the following standards:

- IEC 60601-1:1988+Al: 1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2001 + A1:2004 Medical Electrical Equipment – Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- IEC 60601-1-4: 2000 General Requirement for Safety: Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-1-8: 2003 General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment
- IEC 60601-2-30: 1999: Manual, electronic or automated sphygmomanometers
- ISO 9919: 2005: Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- IEC 60601-2-49: 2001 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment.

Clinical performance data:

No clinical studies were utilized for the purpose of obtaining safety and/or efficacy data.

Conclusions: The intended use and the technological characteristics of the Welch Allyn VSM 6000 device are the same as the predicate devices and the product is as safe and effective as the predicate. Therefore Welch Allyn believes the Welch Allyn VSM 6000 series device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 8 2010

Welch Allyn, Inc.
c/o Mr. Daniel Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 E Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K101445
Trade/Device Name: Vital Signs Monitor - VSM 6000 Series
Regulatory Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: May 21, 2010
Received: May 24, 2010

Dear Mr. Lehtonen:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101445

4. Statement of Indications For Use

510(k) Number (if known): _____

Device Name: Vital Signs Monitor 6000 Series

Indications For Use:

The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. This product is available for sale only upon the order of a physician or licensed health care professional.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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 K101445