

3. Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92. Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness, is outlined below.

Date Prepared: November 7, 2006

Name of Submitter: Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107 USA

Contact:
Jeffrey W. Wagner, Director, Regulatory Affairs
Phone: (503) 530-7909
Fax: (503) 526-4901

Device Proprietary Name: VSM, Vital Signs Monitor, Model 53000 Series (VSM 300)

Classification Name: The Vital Signs Monitor is classified under:
Monitor, Physiological, Patient, (without Arrhythmia Detection or Alarms), 21 CFR 870.2300, Product Code MWI;
Noninvasive Blood Pressure Measurement System, 21 CFR 870.1130, Product Code DXN;
Oximeter, 21 CFR 870.2700, Product Code DQA; and
Thermometer, Electronic, Clinical, 21 CFR 880.2190, Product Code FLL

Common/Usual Names: Multi-parameter Physiological Patient Monitor,
Noninvasive Blood Pressure Measurement System,
Pulse Oximeter,
Electronic Thermometer

Predicate Device: The predicate device is Welch Allyn Protocol, Inc.'s VSM Vital Signs Monitor, Model 53000 Series, which was cleared for marketing under 510(k) K031740. The subject device incorporates a modified noninvasive blood pressure (NIBP) module. The intended use of the predicate device has not changed as a result of this modification.

Device Description:

The VSM, Vital Signs Monitor, Model 53000 Series, (VSM 300) provides real time monitoring and display of noninvasive blood pressure (NIBP), pulse rate, body temperature and noninvasive oxygen saturation of arteriolar hemoglobin (SpO₂).

- NIBP – Noninvasive Blood Pressure is intended to noninvasively measure systolic, diastolic and mean arterial pressures (MAP).
- Temperature – Intermittent thermometer takes patient temperature in oral, axillary or rectal mode.
- SpO₂ – Pulse Oximetry channel is intended to noninvasively measure oxygen saturation of arteriolar hemoglobin at a peripheral measurement site.

The subject device is a modified version of the Model 53000 Series vital signs monitor, which was cleared for marketing under 510(k) K031740. The Model 53000 Series vital signs monitor has been changed to incorporate a modified NIBP module. The modified and existing NIBP modules are similar in their basic functionality. The modified NIBP module contains an updated safety processor, which replaces a discontinued safety processor. Both safety processors belong to the same microcontroller family. The modified NIBP module also incorporates other minor software and hardware changes, including the addition of a Resistor-Capacitor network to reduce sensitivity to external vibration. The modified Vital Signs Monitor, Model 53000 Series (VSM 300) monitor communicates to the user the same basic information as the Model 53000 Series vital signs monitor, specifically:

- Saturation,
- Pulse rate,
- Pleth waveform,
- Trigger waveform for audible beep, and
- Status information (e.g., sensor type, board integrity).

In addition, the user display of the above information (e.g., saturation, pulse rate, error codes) remains unchanged.

Intended Use:

The VSM series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, body temperature, 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 device is available for sale only upon the order of a physician or licensed health care professional.

Technological Characteristics:

The modified Model 53000 Series (VSM 300) vital signs monitor (i.e., the subject device) has the same technological characteristics as originally cleared with the predicate device.

- It has the same basic design;
- It uses the same energy source;
- It uses the same operating principle;
- It incorporates the same basic materials; and
- It is packaged using the same materials and processes.

Based on these similarities, Welch Allyn believes that the subject device is substantially equivalent to the VSM Model 53000 Series that was cleared for marketing under K031740.

Performance Data:

The subject device has been tested in accordance with the following Welch Allyn documents using production equivalent units prior to market release.

831-1212-00	PE TEST REPORT:VSM III,NIBP/POEM II
831-1213-00	Test Report: VSM III Safety Testing for POEM II
831-0783-07	TEST RPT,EMC,VSM III POEM II,EN60601-1-1-2:2001
831-1245-00	VSM 300 SERIES NIBP ANSI/AAMI SP10:2002 TEST REPORT
831-1251-00	VSM 300 SERIES ANSI/AAMI SP10:2002 NEONATE TEST REPORT

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Welch Allyn Protocol's product development procedure. Welch Allyn Protocol's Quality System conforms to 21 CFR 820 and is certified to ISO 13485:2003.

Conclusions:

Based on the information contained herein, we conclude that the changes are minor and that the subject device is substantially equivalent to the predicate device. The intended use of the Vital Signs Monitor, Model 53000 Series, as described in its labeling, has not changed as a result of this modification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2006

Welch Allyn Protocol, Inc.,
c/o Mr. Jeffrey W. Wagner
Director, Regulatory Affairs
8500 SW Creekside Place
Beaverton, OR 97008-7107

Re: K063419

Trade Name: VSM-Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II
Product Code: MWI
Dated: November 7, 2006
Received: November 13, 2006

Dear Mr. Wagner:

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

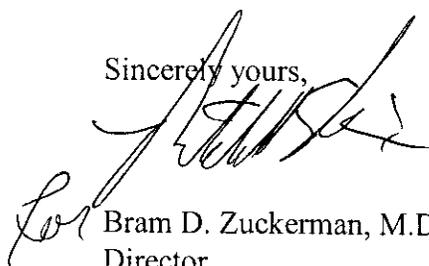
Page 2 – Mr. Wagner

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure



4. Statement of Indications for Use

Applicant:

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

510(k) Number: K063419

Device Name: VSM, Vital Signs Monitor, Model 53000 Series (VSM 300)

Indications for Use:

The VSM series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, body temperature, 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 device is available for sale only upon the order of a physician or licensed health care professional.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 K063419