II. 510(k) Summary

AUG 18 2004

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles, New York 13153

Contact Person: David Klementowski
Regulatory Affairs Manager

Date Prepared: 20 February 2004

Proprietary Name: Welch Allyn Spot Ultra Vital Signs

Common Name: Vital Signs Measurement Device

Classification Name: Class II 870.1130 Noninvasive Blood Pressure System

Predicate Device: Welch Allyn Spot Vital Signs
Welch Allyn, Inc.
510(k) Document Control Number *K002530 and K024005*

Description of the Device:

Indications For Use of the Device:

The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO2) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Contraindication For Use of the Device:

SPOT VITAL SIGNS ULTRA IS NOT INTENDED TO MEASURE BLOOD PRESSURE ON NEONATAL PATIENTS. Welch Allyn defines neonates as children 28 days or less of age if born at term (37 weeks gestation or more); otherwise up to 44 gestational weeks. This definition comes from the AAMI SP10:2002 standard.

Spot Vital Signs Ultra is designed for medical clinician use. Although this manual may illustrate medical spot check techniques, only a trained clinician who knows how to take and interpret a patient's vital signs should use this system. Spot Vital Signs Ultra is not intended for use in environments that are without health care practitioner supervision.

Spot Vital Signs Ultra is not intended for continuous monitoring and is therefore not defibrillator proof. **Do not leave the device unattended while taking measurements on a patient.**

Spot Ultra is not intended for use during the transport of a patient.
WARNING: This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.

Blood Pressure Warnings
To ensure pediatric blood pressure accuracy and safety, the Small Child Durable One-Piece Cuff (5082-203-4) and the Small Child Disposable One-Piece Cuff (5083-93-4) are the smallest cuffs approved for use with young children and infants. The child's arm must fit within the range markings on the cuff.

You may experience inaccurate blood pressure measurements if cuffs and/or hoses other than those provided for Spot Vital Signs Ultra by Welch Allyn are used. To ensure patient safety, use only accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO2 sensors, etc.) recommended for or supplied with Spot Vital Signs Ultra.

Avoid compression of the cuff tubing or pressure hose of Spot Vital Signs Ultra. Compression of the cuff tubing or pressure hose may cause system errors to occur in the device.

Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors with warm air. Check all operating functions.

A qualified service person should check any Spot Vital Signs Ultra that has been dropped or damaged to ensure proper operation prior to use.

Every three months, inspect the temperature probe, SpO2 cord, and accessories for fraying or other damage. Replace as necessary.

Do not use Spot Vital Signs Ultra on patients who are linked to heart/lung machines.

There are no user-serviceable parts inside the device other than battery replacement.

Spot Vital Signs Ultra does not operate effectively on patients who are experiencing convulsions or tremors.

This device complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices.

As a precaution, avoid using this device in close proximity to other equipment.

This device is not intended for hand-held use during operation.

Welch Allyn recommends that the battery is left in the device, regardless if the device is not used for long periods of time. There is no hazard of leaving the battery in the device.

Using unapproved Welch Allyn accessories with Spot Vital Signs Ultra can affect patient and/or operator safety.

Do not autoclave.

Welch Allyn is NOT responsible for the integrity of any wall-mounting interface. Welch Allyn recommends that the customer contact their Biomedical Engineering Department or maintenance service to ensure professional installation for safety and reliability of any mounting accessory

Patients that are experiencing moderate to severe arrhythmias may give inaccurate blood pressure measurements.

When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.

SpO2 Warnings

The operation of the SpO2 sensor in MRI environments is specifically not recommended.

Only use Spot Vital Signs Ultra with Nellcor or Masimo pulse oximetry option with Nellcor or Masimo brand sensors and accessories, respectively. Using the wrong or unapproved sensors or cables may cause improper performance.

The SpO2 sensor and extension cables are intended for use only for pulse oximetry measurements. Do not attempt to connect these cables to a PC or any similar device.

Before using, carefully read the sensor Operator's Manual, including all warnings, cautions, and instructions.

Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed optical components.

Incorrect application or a long duration of use of an SpO2 sensor may cause tissue damage. Inspect the sensor site periodically as directed in the sensors' direction for use.

SpO2 readings and pulse signal is affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Do not immerse or wet the sensor.

Do not use the pulse oximetry cable or power cord to lift the pulse oximeter because the cable or cord may disconnect from the pulse oximeter, causing the pulse oximeter to drop on the patient.

The SpO2 is NOT intended for use as an apnea monitor.

Consider the pulse oximeter an early warning device. As a trend toward patient hypoxemia is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.

Carefully route patient cabling to reduce the possibility of patient enlargement or strangulation.

Severe anemia may cause erroneous SpO2 readings.

Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.

Temperature Warnings
SureTemp Plus™
Use single-use, disposable probe covers to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

Do not take a patient's temperature without using a disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, or erroneous temperature readings.

Long-term continuous monitoring beyond three to five minutes is not recommended in any mode.

Biting the probe tip while taking a temperature may result in damage to the probe.

Oral/axillary probes (blue ejection button at top of probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the probe at the wrong site will result in temperature errors. Use of the incorrect removable probe well could result in patient cross-contamination.

The thermometer connectors and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all functions for proper operation.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

The SureTemp Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. A qualified service technician must check any SureTemp Plus thermometer that is dropped or damaged to ensure proper operation prior to further use. Do not use the thermometer if you notice any signs of damage to the probe. Contact the Welch Allyn Customer Service Department for assistance.

Do not autoclave.

General Cautions
If the accuracy of any measurement is in question, check the patient's vital sign(s) with an alternate method, then check to make sure the device is functioning properly.

Place the device on a secure surface or use one of the optional mounting accessories.

Do not place fluids on or near the device.

Blood Pressure Cautions
Minimize extremity and cuff motion during blood pressure determinations.

If the blood pressure cuff is not at heart level, note the difference in reading due to the hydrostatic effect. Add the value of 1.80 mmHg (.2 kPa) to the displayed reading for every inch (2.5 cm) above heart level. Subtract the value of 1.80 mmHg (.2 kPa) from the displayed reading for every inch (2.5 cm) below heart level.

Proper blood pressure cuff size and placement is essential to the accuracy of the blood pressure determination. See "Chart for Determining Cuff Size" on page 23 for cuff sizing information.

Pulse Oximetry Cautions
The pulse oximeter is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboy hemoglobin or methmoglobin may affect the accuracy of the measurement.

Some intravascular dyes, depending on the concentration, may affect the accuracy of the SpO2 measurement. Some sensors may not be appropriate for a particular patient. If at least 10 seconds of perfusion pulses cannot be observed for a given sensor, change sensor location or sensor type for perfusion to resume.

The sensor disconnect message indicates that the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable, or both.

> NOTE: Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring.

Technological Characteristics:

The Welch Allyn Spot Ultra Vital Signs Device utilizes an Oscillometric BP Algorithm and temperature technology, similar to Spot Vital Signs and utilizes the same SpO2 OEM as the Welch Allyn Spot Vital Signs. The new Spot Ultra Vital Signs will incorporate a new temperature module (Braun 4000) and a new SpO2 OEM module the Masimo SET as options. The FDA, under 510(k) numbers K002530 and K024005, approved Spot Vital Signs. The following table summarizes the similarities between the Welch Allyn Spot Vital Signs Device and the new Welch Allyn Spot Ultra Vital Signs Device.

Table 1

Specifications & Technological Comparison Between the Welch Allyn Spot Vital Signs Device and the Welch Allyn Spot Ultra Vital Signs Device.

	Welch Allyn Spot Vital Signs Device	**Welch Allyn Spot Ultra Vital Signs Device**
Blood Pressure		
BP Determination Method	Oscillometric	Oscillometric
Auto Zero	Yes	Yes
Initial Cuff Inflation	160 (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.	Intelligent Target inflation, (which can return a BP reading) or 160 mmHg (Default). Operator may change this default. Options are 120, 140, 160, 180, 200, 240 and 280.
Measurement Range		
Systolic	60-250 mmHg	60-250 mmHg
Diastolic	30-160 mmHg	30-160 mmHg
Heart Rate (Using Oscillometric measurement)	40-200 bpm	35-199 bpm
Measurement Accuracy		
Cuff Pressure	+/- 3 mmHg	+/- 3 mmHg
Blood Pressure	AAMI SP10-1992	AAMI SP10-2002
Heart Rate	+/- 5% (BP Determination)	+/- 5% (BP Determination)

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
BP Time Intervals (Min.)	NA	NA
Measurement time (sec.)	20-45 typical, 165 max.	15 to 30 typical, 150 max.
Mean Arterial Pressure	Calculated	Calculated
Nellcor® OEM SpO2		
SpO2 Measurement	Yes	Yes
OEM Model Used	MP506	MP506
Measurement Range		
SpO2	40-100%	40-100%
Heart Rate	25-245 bpm	25-245 bpm
Measurement Accuracy		
SpO2	70-100% +/- 3% <70% unspecified	70-100% +/- 3% <70% unspecified
Heart Rate	+/- 3 bpm	+/- 3 bpm
Massimo OEM SpO2		
Spo2 Measurement	No	Yes
OEM Model Used	NA	NCT-11
Measurement Range		
SpO2	NA	40-100%
Heart Rate	NA	25-245 bpm
Measurement Accuracy		
SpO2	NA	70-100% +/- 3% <70% unspecified
Heart Rate	NA	+/- 3 bpm
SureTemp® OEM Temperature		
Temperature	Yes	Yes
Measurement Range	84°F (30°C) to 109.4°F (43.0°C)	80.0° to109.4° F (34.5°-43.0°C)
Measurement Accuracy	per ASTM E1112-86 (1991)	per ASTM E1112-00 (2000)
Temperature Determination	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes	Normal Mode: 4 sec (Oral), 10 sec (Axillary), 15 sec (Rectal) Monitor Mode: 3 minutes
Braun 4000 IR Thermometer		
Temperature	No	Yes
Measurement Range	NA	68° to 108° F / 20° to 42.2° C
Measurement Accuracy	NA	Per EN12470
Temperature Determination	NA	Ear IR
HHP 3800PDF Bar Code Scanner	No	Yes

	Welch Allyn Spot Vital Signs Device	Welch Allyn Spot Ultra Vital Signs Device
Overall System		
Patient Population	Pediatric/Adult	Pediatric/Adult
Data Communications	IR wireless Capable Communication	Wireless (802.11b) Capable Communications, USB 1.1 Communications and/or RS232 Communications
Display Type	Custom LCD	Custom LCD
Low Battery Indicators	Symbol on LCD begins to flash when low battery voltage is detected	Symbol on LCD begins to flash when low battery voltage is detected
Number of readings stored in memory	No readings are stored	Last 50 readings are stored
Battery Charge Time	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously	90% Capacity in 12 hours. Unit will operate and charge the battery simultaneously
Battery Life	150 typical readings	120 typical readings
Warranty	Two Years	Two Years
Height	9.70 inches (24.64 cm)	25 cm
Length	5.72 inches (14.53 cm)	15 cm
Depth	4.73 inches (12.01 cm)	10 cm
Weight	4.25 lbs	6.5 lbs
Operating Temperature	10 to 40 °C (except temperature which is 16 to 40 °C)	10 to 40 °C
Humidity Range	15 to 90% RH non-condensing	15 to 90% RH non-condensing
Altitude Range	-170 m (557 ft) to +4877 m (16,000 ft)	-170 m (557 ft) to +4877 m (16,000 ft)
Storage Temperature	-20 to 50 C	-25 to 55 C
Battery	Lead Acid, with external recharge capability	Lead Acid, with external recharge capability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2004

Welch Allyn, Inc.
c/o Mr. Christopher Klaczyk
Senior Regulatory Engineer
4341 State Street Road
P.O. Box. 220
Skaneateles Falls, NY 13153-0220

Re: K040490
Trade Name: Welch Allyn Spot Ultra Vital Signs Device
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Klaczyk:

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) 594-4646. 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 may be obtained 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

K040490

VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn Spot Ultra Vital Signs Device

Indications for use: The Spot Vital Signs Ultra automatically measures systolic and diastolic pressure, Mean Arterial Pressure (MAP), pulse rate, temperature (oral, adult axillary, pediatric axillary, rectal, and ear), and pulse oximetry (SpO2) of adult and pediatric patients. Furthermore, Spot Vital Signs Ultra allows the manual entry of height, weight, respiration, and pain level. Spot Ultra also calculates Body Mass Index (BMI) following height and weight entry.

The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

Prescription Use X Or Over-The-Counter Use _____

(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 K040490