K101680
p1/5

Welch Allyn

510(k) Summary

[As described in 21 CFR 807.92]

JUL - 9 2010

Submitted by:

Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person:

Fred Schweitzer
Vice President, QA/RA
Phone: (315) 554-4001
Fax: (315) 685-2532
E-mail: schweitzerf@welchallyn.com

Date Prepared:

June 02, 2010

Trade Name:

Welch Allyn Spot Ultra Vital Signs and Welch Allyn Spot Vial Signs LXi

Common Name:

Spot Vital Signs Measurement Device

Classification Reference:

Class II, 870.1130 Noninvasive Blood Pressure System
Product Code - DXN

Predicate Device:

Welch Allyn Spot Ultra Vital Signs

Welch Allyn, Inc.
510(k) Document Control Number K040490

Welch Allyn

Description of the Device:

The Welch Allyn Spot Ultra Vital Signs (Spot Vital Signs LXi) is not a monitor, but a one-time vital signs measurement device. This product will not have continuous monitoring capability with timed cycle intervals or any various programmable alarm features. Welch Allyn Spot Vital Signs LXi will include Blood Pressure with Temp, as the base feature, SpO_2 is an option.. A mobile stand, custom wall mount, an external printer, a barcode reader, weight scales and 802.11 a,b,g wireless communications are accessories that Welch Allyn Spot Ultra Vital Signs Device can be configured.

The Welch Allyn Spot Vital Signs LXi is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature, and oxygen saturation (spO_2) for adult and pediatric patients. The Welch Allyn Spot Vital Signs LXi will also calculate Mean Arterial Pressure (MAP). All blood pressure, pulse, temperature, and SpO_2 values are displayed on a large, easy-to-read LCD display, and may be printed via an external thermal printer, as desired. The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Spot Ultra Vital Signs Device convenient for many locations. The Spot Vital Sign LXi will also allow for data entry for weight, height, pain and will calculate Body Mass Index (BMI).

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 (SpO_2) 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.

Technological Characteristics:

The Welch Allyn Spot Vital Signs LXi is intended for use by trained operators in healthcare facilities.

The Welch Ally Spot Ultra Vital Signs Device utilizes an Oscillometric Blood Pressure Algorithm, SpO_2 OEM and temperature module technology. The original (predicate) device was cleared under FDA 510(k) number K040490. The dame fundamental scientific technology and intended use are the same for the modified device as the predicate device..

Welch Allyn

The following table summarizes the similarities between the subject Welch Allyn Spot Vital Signs LXi and the predicate Welch Allyn Spot Ultra Vital Signs Device (K040490).
There are no hardware or software modifications to the Spot Ultra Vital Signs Device.

*Welch Allyn Spot Ultra Vital Signs Device (K040490) Substantial Equivalence Comparison		
Subject Area	**Similarities**	**Differences**
Indications for Use	Same for Spot Vital Signs Blood Pressure measurement – automatically measures systolic and diastolic pressure and calculated Mean Arterial Pressure (MAP)	There are no differences in indications for use from what has been previously cleared by the FDA.
Target Population	Remains the same for Spot Vital functions	There are no changes from what has been previously cleared by the FDA.
Where Used	Spot Vital Signs functions remain the same. Where used for the Vital Signs has not changed.	No differences
Design	Welch Allyn Spot Vital Signs functions continue to use the same design. Blood Pressure interface functionality also remains the same.	No differences Document objective evidence that the STEP Blood Pressure (BP) mode of the SURE BP algorithm is functionally equivalent to the SURE BP Mode (AAMI SP10 – Validation Report)
Human Factors	All hardware and software functionality are identical	There are no changes from what has been previously cleared by the FDA.
Performance	The Blood Pressure interface performances have not changed.	There are no changes from what has been previously cleared by the FDA. Document objective evidence that the STEP Blood Pressure (BP) mode of the SURE BP algorithm is functionally equivalent to the SURE BP Mode (AAMI SP10 – Validation

Welch Allyn

*Welch Allyn Spot Ultra Vital Signs Device (K040490) Substantial Equivalence Comparison		
Subject Area	**Similarities**	**Differences**
		Report)
Materials	All materials are the same as referenced to the original FDA	None
Efficacy	Efficacy of existing Spot Vital Signs products and Blood Pressure interface has not changed.	None
Sterility	Not Applicable	Not Applicable
Biocompatibility	All materials are the same as referenced to the original FDA	None
Safety	There are no changes from what has been previously cleared by the FDA.	None
Compatibility	Hardware & Software compatibility has not changed.	There are no changes from what has been previously cleared by the FDA.
Packaging	Packaging for existing Spot Vital Signs hardware products have not changed.	None

The Welch Allyn Spot Vital Signs LXi has equivalent vital signs measurement as the Welch Allyn Spot Ultra Vital Signs (K040490).

They are no technological differences between the two devices that affect the safety or effectiveness of the device.

Summary of Effectiveness:

The Welch Allyn Spot Vital Signs team has determined that the software "Level of Concern" is Moderate.

The document objective evidence (AAMI SP10 – validation report) that the STEP Blood Pressure (BP) Mode of the SURE BP algorithm is functionally equivalent to the SURE BP Mode and cleared per K040490. A copy of the specification and validation from that study, as presented for the Welch Allyn Spot Ultra Vital Signs submission K040490.

All requirements of the recognized and applicable standards are in compliance: SP10 (AAMI/ANSI), UL 60601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4.

Additionally, risk management (risk, SFMEA and safety analysis) activities have been conducted in accordance with ISO 14971 Medical Devices – Application of risk management to medical devices and comply with IEC 60601-1-4 Medical Electrical

Welch Allyn

Equipment Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems.

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

JUL - 9 2010

Welch Allyn, Inc.
c/o Mr. Huy Doan
Director, Corporate Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K101680
Trade/Device Name: Welch Allyn Spot Ultra Vital Signs/Spot Vital Signs LXi
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN, DQA, FLL
Dated: June 2, 2010
Received: June 15, 2010

Dear Mr. Doan:

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.

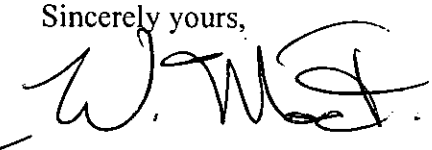
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

K101680

Welch Allyn

Indications for Use Statement

510(k) Number (if known):

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 (SpO_2) 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K101680