K093907

Welch Allyn

6. Premarket Notification [510(k)] Summary

Date: February 3, 2010

APR 1 4 2010

Submitted By: Welch Allyn, Inc.
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Contact: Huy Doan, Senior Manager, Regulatory Affairs

Common Name: Non-invasive Blood Pressure (NIBP) Device
Trade Name: Welch Allyn Non-invasive Blood Pressure (NIBP) Device
Classification Name: Noninvasive blood pressure measurement system
Class II; Product Code: DXN- 21 CFR 870.1130

Predicate Devices: Modification to VSM- Vital Signs Monitor (VSM 300) (K063419)
Welch Allyn Spot Ultra Vital Signs Device (K040490)

Description: The Welch Allyn NIBP device consists of 1) a software program running on a laptop computer; 2) an NIBP module which measures and reports the patient's blood pressure and pulse rate readings.

The device is intended to operate with a series of standard blood pressure cuffs and blood pressure tubing.

The Welch Allyn NIBP device is designed to non-invasively measure systolic and diastolic blood pressure and pulse rate for adult, pediatric and neonatal patients using the oscillometric method. The Welch Allyn NIBP device will also calculate Mean Arterial Pressure (MAP). All blood pressure and pulse values are displayed on the large, easy-to-read LCD display of the laptop computer.

The Welch Allyn NIBP device is intended for use in a wide variety of health care settings. This includes hospital departments; alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes.

Indications for Use:

The Welch Allyn Non-Invasive Blood Pressure device is intended to be used by clinicians and medically qualified personnel for the acquisition and attended monitoring of noninvasive blood pressure and pulse rate of neonatal through adult patients. The Welch Allyn Non-Invasive Blood Pressure device may be used for treatment and diagnostic spot NIBP measurements or attended NIBP monitoring in hospital general wards, clinics, and doctor's offices.

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Contraindications for Use:

The Welch Allyn Non-Invasive Blood Pressure device is not intended for use with severe arrhythmia. The Welch Allyn Non-Invasive Blood Pressure device is not intended for patients who are experiencing convulsions or tremors.

Technological Characteristics:

The Welch Allyn NIBP Device utilizes an Oscillometric BP Algorithm that is equivalent to the BP Algorithm in the Spot Ultra Vital Signs and Welch Allyn VSM 53000. The Welch Allyn NIBP Device is powered from USB power from the Laptop PC. It uses the same operating principle and incorporates the same basic material. 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+Al: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
- AAMI SP10: 2002: Manual, electronic or automated sphygmomanometers (A1:2003, A2:2006)

Clinical performance data:

Clinical safety and performance requirements were met based on the ANSI/AAMI SP10: 2002 (R2008) standard for Manual, electronic or automated sphygmomanometers + Amendment 1 & 2 standards

Conclusions:

The intended use and the technological characteristics of the Welch Allyn NIBP device are the same as the predicate devices and the product meets FDA's recognized concensus standards. Therefore Welch Allyn believes the Welch Allyn NIBP 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 W-O66-0609
Silver Spring, MD 20993-0002

APR 1 4 2010

Welch Allyn, Inc.
c/o Mr. Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K093907
Trade/Device Name: Welch Allyn Non-Invasive Blood Pressure (NIBP) Device
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: March 18, 2010
Received: March 22, 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Indications for Use

510(k) Number (if known): K093907

Device Name: Welch Allyn Non-invasive Blood Pressure (NIBP) Device

Indications for Use:

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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 K093907