DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 19, 2014

Welch Allyn, Inc.
Kevin Crossen
Director Regulatory Affairs
4341 State St. Rd.
P.O. Box 220
Skaneateles Falls, New York 13153-0220

Re: K142356
Trade/Device Name: Connex Spot Monitor, 901058 Vital Signs Monitor Core
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: December 2, 2014
Received: December 3, 2014

Dear Kevin Crossen,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Melissa A. Torres -S

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

Indications for Use

510(k) Number (if known): K_____

Device Name: Welch Allyn Connex® Spot Monitor

Indications for Use:
The Connex Spot monitors are 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 med/surg. floors, general hospital and alternate care environments.

Prescription Use ____×_____	AND/OR	Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D)		(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)

Traditional 510(k) Premarket Notification
for
Connex® Spot Monitor
Section 07

510(k) Summary (per 21 CFR 807.92)

510(k) Summary

[As described in 21 CFR 807.92]

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

Contact Person: Kevin Crossen
Director Regulatory Affairs
Phone: (315) 685-2609
Fax: (315) 685-2532
E-mail: Kevin.Crossen@welchallyn.com

Date Prepared: August 20, 2014

Trade Name: Connex® Spot Monitor
901058 Vital Signs Monitor Core

Common Name: Monitor, physiological, patient (without arrhythmia detection or alarms)

Classification Reference: Class II, monitor, physiological, patient (without arrhythmia detection or alarms) (21 CFR 870.2300, Product Code: MWI)

Predicate Device: Connex® Vital Signs Monitor 6000 Series
510(k) Number: K132808
Cardiovascular, 21 CFR 870.2300
Class II, MWI

Description of the Device:

The Welch Allyn Connex® Spot Monitor (CSM) is an integrated, configurable monitor designed to facilitate the workflows of its users.

The Welch Allyn Connex® Spot Monitor is intended to be used by clinicians and medically qualified personnel for measuring or monitoring patient vital signs. The particular vital sign measurements available are determined by the sensor/processing technology integrated into the base unit including;

- NIBP, provides measurements of noninvasive blood pressure and pulse rate,
- SpO_2, provides pulse rate and noninvasive functional oxygen saturation of arteriolar hemoglobin,
- Thermometer measures temperature, e.g., in neonatal, pediatric, and adult patients.

- The Custom Scores option provides custom calculations based on patient vital sign values and modifiers determined by the user.

The CSM can also display and transmit patient data that is electronically or manually entered from external and accessory devices, e.g., weight and height data, barcode scanner, and other patient or facility information. Data can be transmitted electronically via USB, wired Ethernet, or wireless communications including Bluetooth, for example, to electronic record systems and for remote display and alarming (e.g., central station).

Indications for Use:

The Connex Spot monitors are 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 med/surg. 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.

Contraindications:

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

For contraindications of SpO2 sensors, consult the sensor manufacturer's directions for use.

Technological Characteristics:

The CSM is essentially the same device as the CVSM offering utilizing a subset of Spot check only sensors in a slightly different form factor. There are three main technological differences from the predicate CVSM. Instead of utilizing interchangeable modules, the CSM integrates many of the vital sign features into the device. In addition, the CSM and the CVSM utilize different operating systems. Finally, the CSM adds the option of having wireless Bluetooth capability in addition to wireless radio. CSM can be configured to have custom scoring that is determined by the customer.

Performance Data:

Biocompatibility testing
The CSM does not contact the patient. The accessories used with the CSM have been cleared under previous 510(k)’s and have been tested in accordance with ISO-10993.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Animal Study

No animal studies were conducted as part of submission to prove substantial equivalence. .

Clinical Studies

No clinical studies were conducted as part of submission to prove substantial equivalence.

Non-Clinical Tests:

The Welch Allyn Connex® Spot Monitor was tested to evaluate its safety and effectiveness based on the following standards:

Standards, Electrical Safety and Electromagnetic Compatibility (EMC)

Standard	Version	Title
IEC 60601-1	3ED 2005, AMD 1 2012	Medical electrical equipment - part 1: general requirements for basic safety and essential performance
IEC 60601-1-2	3 ED 2007	Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
IEC 60601-1-8	2nd edition 2006	Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 80601-2-30	1ED 2009 COR 1 2010	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 80601-2-61	1ED 2011	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-56	2009 First edition	Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
EN/ISO 14971	2007	Medical devices – application of risk management to medical devices

Additional performance Bench Testing:

Report DIR --- Description	Objective of the Test	Conclusions
Device Ship Test ISTA-2A and ISTA 1A	Ensure device, enclosed in the selected shipping container, meets ISTA 2A 2011 specifications.	Pass
SpO2 Functional Accuracy testing	Ensure the accuracy and communication of the OEM FDA cleared SpO2 technologies per the FDA SpO2 guidance; Pulse Oximeters-Premarket Notification Submissions Guidance for Industry and Food and Drug Staff, March 4, 2013.	Pass
Wireless radio communication	Ensure device can communicate via wireless radio in its intended environment	Pass
Bluetooth radio communication	Ensure device can communicate via Bluetooth radio in its intended environment	Pass
Formative Usability Testing	Ensure device meets the user needs	Pass

Device Comparison

The Welch Allyn Connex® Spot Monitor is substantially equivalent to the Welch Allyn Vital Signs Monitor 6000 Series monitor (K132808) The indications for use of the CSM is a subset of the indications for use of the CVSM. The CSM is able to capture the vital sign measurements of SpO2, blood pressure and temperature. The algorithms for these vital signs measurement are unchanged from CVSM. The CSM vital signs technologies are integrated into the device. The CSM can be configured with custom scores, wireless radio and Bluetooth. The CSM provides three SpO2 options compared to two in the CVSM.

Similarities between the subject device and the predicate device. The subject device and the predicate device have the same :

- NIBP Technology
- SpO2 Technology (Masimo, Covidien)
- Temperature Technology
- Wireless radio communication
- LCD touch screen

Differences between the subject device and the predicate device. The subject device has the following:

- Linux operating system
- Integrated technology

- Nonin additional SpO2 option
- Additional battery power source
- Bluetooth capability

Conclusion

Based on the information presented in this 510(k) premarket notification the Connex® Spot Monitor (CSM) is considered substantially equivalent. The CSM is as safe and effective as the currently marketed CVSM predicate device (K132808). The differences between the hardware, software, and mechanical aspects of the CSM and the predicate CVSM device were successfully tested with the relevant standards and FDA guidance, and does not affect equivalent safety and effectiveness or raise new questions of safety or effectiveness.