



December 20, 2024

Welch Allyn, Inc.  
Beth Rice  
Manager, Regulatory Affairs  
4341 State Street Road  
Skaneateles Falls, New York 13153

Re: K241411

Trade/Device Name: Welch Allyn Connex® Spot Monitor; 901058 Vital Signs Monitor Core (CSM)  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI, DQA, DXN, FLL, BZQ  
Dated: May 10, 2024  
Received: May 17, 2024

Dear Beth Rice:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Robert T. Kazmierski -S**

for

LCDR Stephen Browning  
Assistant Director  
Division of Cardiac Electrophysiology,  
Diagnostics, and Monitoring Devices  
Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K241411

Device Name

Welch Allyn Connex® Spot Monitor; 901058 Vital Signs Monitor Core (CSM)

Indications for Use (Describe)

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 (SpO<sub>2</sub>), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Monitoring respiration rate from photoplethysmogram (Masimo RRp®) is indicated for adult and pediatric patients greater than two years old. The most likely locations for patients to be monitored are general medical or surgical floors and general hospital and alternate care environments.

This product is available for sale only upon the order of a physician or licensed health care professional.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

### CONTACT DETAILS

Beth Rice  
Manager, Regulatory Affairs  
Welch Allyn Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153-0220

### DEVICE NAME

Device Trade Name: Welch Allyn Connex® Spot Monitor; 901058 Vital Signs Monitor Core (CSM)

Common Name: Cardiac monitor (including cardiometer and rate alarm)

Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Regulation Number: 21 CFR 870.2300

Product Code(s): MWI, DQA, DXN, FLL, BZQ

**Table 1. Legally Marketed Predicate Devices**

Predicate Number	Predicate Trade Bane	Product Code
K142356	Welch Allyn Connex Spot Monitor	MWI
K193242	Masimo Rad-97 Pulse CO-Oximeter and Accessories, Masimo Radical-7 Pulse	MWI

### DEVICE DESCRIPTION SUMMARY

Welch Allyn Connex® Spot Monitor (CSM) is an integrated, configurable vital signs monitor. CSM is intended to be used by clinicians and medically qualified personnel for measuring or monitoring patient vital signs. The specific vital sign measurements available are determined by the sensor/processing technology integrated into the base unit including:

- Noninvasive blood pressure (NIBP) provides measurements of noninvasive blood pressure and pulse rate
- Spo2 provides pulse rate, respiration rate, and noninvasive functional oxygen saturation of arteriolar hemoglobin
- Thermometer measures temperature in neonatal, pediatric, and adult patients

- Respiration rate from photoplethysmogram (RRp)
- The custom scores option provides custom calculations based on patient vital sign values and modifiers determined by the user

The CSM 1.53, in the same manner as the CSM predicate device, can display and transmit patient data that is electronically or manually entered from external and accessory devices, including weight and height data, manually entered respiration rate, barcode scanned patient and clinician data, and other patient or facility information to a connected Host system. Data is transmitted electronically via USB, Wi-Fi, Bluetooth or ethernet communications to electronic record systems, and for remote display and alarming (e.g., at a central station).

### **INTENDED USE/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 (SpO<sub>2</sub>), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Monitoring respiration rate from photoplethysmogram (Masimo RRp®) is indicated for adult and pediatric patients greater than two years old. The most likely locations for patients to be monitored are general medical or surgical floors and general hospital and alternate care environments.

This product is available for sale only upon the order of a physician or licensed health care professional.

### **INDICATIONS FOR USE COMPARISON**

The indications for use has changed to add monitoring of respiration rate from photoplethysmogram (Masimo RRp®). This difference does not constitute a new intended use of a patient physiological monitor, designed for professional use in a clinical setting.

### **TECHNOLOGICAL COMPARISON**

The subject device and the predicate device share many of the same attributes for patient vital signs. monitoring, including the monitoring algorithms, power source, sensors and interfaces.

The subject device, CSM 1.53, includes the following technology updates:

- Masimo pulse oximetry sensing technology (K193242) offering measurement of respiration rate from photoplethysmogram (RRp)
- An additional thermometry option was added for the device by adding an already cleared Braun Pro 6000 Infrared Thermometer
- Additional bar code scanner options
- Additional stand/mounting options
- Additional weight scale options

All updates were implemented through the design control process and verified to not impact safety and efficacy of the device.

### **NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS**

- Non-clinical testing was performed on the CSM to verify safety and efficacy of the device. The CSM was tested according to the following standards.
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (FDA recognition Number 19-49)
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (FDA recognition Number 5-132)
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION 60601-1-8 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 (FDA recognition Number 5-131)
- ANSI AAMI IEC 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (FDA recognition Number 3-123)
- IEC 80601-2-49:2018 Particular requirements for the basic safety and essential performance of multifunction patient monitors
- 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. (FDA recognition Number 6-421)

- ISO 80601-2-56 Second edition 2017-0380601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) (FDA recognition Number 1-139)
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices (FDA recognition Number 5-129)
- EC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes [Including Amendment 1 (2016)] (FDA recognition Number 13-79)
- AAMI TIR69: 2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. (FDA recognition Number 19-22)
- ANSI/USEMCSC C63.27 2021 American National Standard for Evaluation of Wireless Coexistence (FDA recognition Number 19-48)
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems (FDA recognition Number 19-33)
- ANSI AAMI ISO 10993-1:2018 Medical devices - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA recognition Number 2-258)
- ISO 13485:2016 Quality Management system requirements for regulatory purposes

#### General Use

- ISO 14971 Third Edition 2019-12 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA recognition Number 5-125)
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (FDA recognition Number 5-134)
- TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical

electrical equipment and medical electrical systems (FDA recognition Number 19-19)

- FCC Title 47 Subpart B and Subpart C Telecommunications: Subpart B: Unintentional Radiators and Subpart C: Intentional Radiators

The non-clinical tests performed confirm that the subject CSM device is substantially equivalent to the legally marketed predicate CSM (K142356).