October 28, 2022

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

Re: K212473
Trade/Device Name: Welch Allyn Connex Central Station (v.1.8.5)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, MHX
Dated: August 5, 2021
Received: August 6, 2021

Dear Megan Pellenz:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212473

Device Name

Welch Allyn® Connex® Central Station (v.1.8.5)

Indications for Use *(Describe)*

The Connex Central Station is intended to be used by clinicians for the central monitoring of neonatal, pediatric and adult patients in health care facilities. In addition to the central monitoring of patient data and alarms, the Connex software can include optional modules to provide extended recording of patient data, including full disclosure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary- K212473

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Welch Allyn, Inc.
Applicant Address	4341 State Street Road Skaneateles Falls NY 13153 United States
Applicant Contact Telephone	315-569-4257
Applicant Contact	Mrs. Megan Pellenz
Applicant Contact Email	megan.pellenz@hillrom.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Welch Allyn® Connex® Central Station (v.1.8.5)
Common Name	Patient Monitoring Central Station
Classification Name	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulation Number	870.2300
Product Code	MWI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K132807	Welch Allyn® Connex® Central Station (v.1.5)	MWI
K171621	Welch Allyn® Connex® Vital Signs Monitor/CIWS	MHX

Device Description Summary

21 CFR 807.92(a)(4)

Both the Welch Allyn primary predicate and subject Connex Central Station devices are software devices for a Windows-based operating system that provide clinicians with a means to remotely monitor the health of several patients simultaneously.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Connex Central Station is intended to be used by clinicians for the central monitoring of neonatal, pediatric and adult patients in health care facilities. In addition to the central
monitoring of patient data and alarms, the Connex software can include optional modules to provide extended recording of patient data, including full disclosure.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device Connex Central Station and the primary predicate Connex Central Station (K132807) have the same Indications for Use:
The Connex Central Station is intended to be used by clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities.
In addition to the central monitoring of patient data and alarms, the Connex software can include optional modules to provide extended recording of patient data, including full disclosure.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device Connex Central Station and the primary predicate device Connex Central Station (K132807) have the same fundamental technology characteristics. A feature difference is that the subject Connex Central Station device displays ECG physiological parameters received from the Connex Vital Signs Monitor (K171621) while the primary predicate device does not. The addition of the new feature (i.e., ECG parameters) on the subject device does not alter the intended use of the subject device compared to the primary predicate nor does it raise new questions of safety and effectiveness. Specifically, the methods used to add ECG parameters to the central monitoring display of the subject device are the same methods used to display the already cleared parameters on the primary predicate Connex Central Station device. Additionally, the methods used to collect ECG parameters on the CVSM have been cleared under K171621. Thus, to support the addition of the ECG parameters and associated FDA product code MHX to the subject device, the Connex Vital Signs Monitor (K171621), is being used as a secondary predicate device in this submission.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Connex Central Station was tested to evaluate its performance based on the following standards:
IEC 62366-1:2015 Medical Devices – Part 1: Application of usability engineering to medical devices

IEC 60601-1- 8:2012 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 62304:2015 Medical Device Software – Software Life Cycle Processes

IEC 60601-2-27:2011 Medical electrical equipment Part 2-27: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment

ISO 14971:2019 Application of Risk Management to Medical Devices

AAMI 80001-1:2010 Application of risk management for IT networks incorporating medical devices

ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

Software Verification and Validation testing were conducted, and documentation provided within this submission as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Connex Central Station software was considered as a "Major" level of concern since a failure of latent flaw in the software could directly result in serious injury or death to the patient or operator. This level of concern was not changed by the addition of the ECG data feature in version 1.8.5 of the software.

Not Applicable. No clinical studies were utilized for the purpose of obtaining safety and effectiveness data.

Well-established, scientific methods are available and were used to evaluate the new ECG parameter features of the subject device. The methods used to add ECG parameters to the central monitoring display of the subject device are the same methods used to display the already cleared parameters on the primary predicate Connex Central Station device.
The methods used to collect ECG parameters on the Welch Allyn CVSM device have been cleared under K171621. Thus, to support the addition of the ECG parameters and associated FDA product code MHX to the subject device, the Connex Vital Signs Monitor (K171621), is being used as a secondary predicate device in this submission.
The performance of the subject Connex Central Station device was evaluated to the same methods utilized for the primary predicate and/or the secondary predicate. The evaluation methods include IEC 62366-1:2015, IEC 60601-1- 8:2012, IEC 62304:2015, ISO 14971:2019, AAMI 80001-1:2010 Section 3.5, ISO 15223-1:2016 and IEC 60601-2-27:2011 Section 201.12.1.101.6 and FDA Special Controls Guidance Arrhythmia Detector and Alarm - Class II Special Controls Guidance Document for Industry and FDA Staff (October 28, 2003).
The software met the design requirements and performance, functionality, and reliability characteristics. The differences in the technological characteristics with the addition of the ECG parameter into the Connex Central Station do not impact the safety and effectiveness of the subject device. Therefore, it can be concluded the evidence presented in this submission confirms that the Connex Central Station v1.8.5 is substantially equivalent to the primary predicate Connex Central Station v1.5 cleared in K132807.