K132807

WelchAllyn

JAN 31 2014

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:

September 06, 2013

Trade Names:

901066 Monitoring Station
Connex® Central Station

Common Name:

Central Station

Classification Name:

Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

Classification Reference:

Class II, 21 CFR 870.2300, Cardiac monitor (including cardiotachnometer and rate alarm)
Product Code: MWI

Predicate Device:

Connex Workstation
Welch Allyn, Inc.
510(k) Number: K120343
Class II, 21 CFR 870.2300, Cardiac monitor (including cardiotachnometer and rate alarm)
Product Code: MWI

Description of the Device:

Connex Central Station, also known as Monitoring Station, is a Windows-based product that provides clinicians with a means to remotely monitor the health of several patients simultaneously. The Monitoring Station receives patient vital signs and alarm data from patient monitors and spot check devices over a network, then displays the data and sounds audio alarms in a centralized location.

Specific patient populations are determined by the requirements of the devices gathering the patient data.

In the Monitoring Station, there are two possible sources of patient data, namely:

a. Continuous monitoring devices that are attached to the patient, or

b. Episodic measurements taken from devices that may or may not be constantly connected to the patient.

Devices providing the patient data may transfer the data electronically to the hospital network for communication with the Monitoring Station via methods such as USB, wired Ethernet, or wireless communications. The Monitoring Station is wired to the network via Ethernet.

The Monitoring Station can be deployed as either a standalone central station or as a server-based deployment where one or more monitoring stations are connected to a Connex server.

Additionally, a kiosk option may be installed on personal computers (PCs) that are running Windows 7, 64 bit, which allows the user to upload episodic data through a USB port to the Server, via the network.

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.

Contraindications:

There are no known contraindications for use.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate device. The hardware and software functionality of the Monitoring Station remain the same as the cleared device except as described below. The Monitoring Station includes the following new features: support for new patient vital signs data and alarms from a new module, called Early Sense, in the Connex Vital Signs Monitor 6000 Series patient monitor, ability to provide hallway displays that duplicate the content on the Monitoring Station's main display, ability to display patient data graphically, ability to deliver alarm notifications to 3rd party communication systems, and minor software and connectivity enhancements to improve performance and customer experience.

Non-Clinical Tests:

The Monitoring Station was tested to the following standards:

Standard	*Version*	*Title*
IEC 60601-1-1	2 Ed 2000	Information Technology Equipment - Safety - Part 1: General Requirements
IEC 60601-1	2 Ed 1988	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-4	1 Ed 1996	Medical electrical equipment - Part 1-4: Consolidated edition 1.1 - General requirements for safety - Collateral standard: Programmable electrical medical systems
IEC 60601-1-8	1 Ed 2003	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 60601-2-49	1 Ed 2001	Medical Electrical Equipment – Part 2-49: Particular Requirements for the Basic Safety and Essential Performance of Multifunction Patient Monitoring Equipment
EN/IEC 62304	1 Ed 2006	Medical Device Software – Software Life Cycle Processes
ISO 14971	2 Ed 2007	Medical devices - Application of risk management to medical devices

Verification and validation were conducted to ensure expected performance of the Monitoring Station. The following tests were performed:

Test Description	*Test Objective*	*Conclusions*
Alarm Gateway Service Configuration Settings – single central station	Verified that alarm notifications are properly sent to the 3rd party notification system based on whether or not the alarm notifications module is enabled and which alarm priorities are configured in the Monitoring Station to be sent.	Pass

Test Description	*Test Objective*	*Conclusions*
Alarm Gateway Service Configuration Settings – multiple central stations	Verified that the alarm priorities can be configured for each central station's alarm notifications module from the server or any of six central stations. Verified that alarm notifications are properly sent to the 3rd party notification system based on whether or not each alarm notifications module is enabled and which alarm priorities are configured to be sent.	Pass
Disconnection with 3rd Party System - single central station	Verified that alarms are displayed on the 3rd party notification system on the first connection or re-connection. It also verifies that the disconnection event with the 3rd party system is logged in the monitoring station logs.	Pass
Disconnection with 3rd Party System - multiple central stations	Verified that alarms are displayed on the 3rd party notification system on the first connection or re-connection. It also verifies that the disconnection event with the 3rd party system is logged in the monitoring stations logs.	Pass
Physiological and Technical Alarms – single central station	Verified that the physiological and technical alarms triggered from the patient monitors and the monitoring station are delivered to the 3rd party notification system.	Pass
Alarm Logging, Acknowledgment and Response - single central station	Verified that the alarm notification messages are logged with a timestamp in the monitoring station's log. Verified that acknowledgement of receipt of the alarm by the 3rd party notification system is logged in the monitoring station's log. Verifies that the responses sent by the 3rd party notification system on the receipt of the alarm messages are logged in the monitoring station logs.	Pass

Test Description	*Test Objective*	*Conclusions*
AGS Outbound Licensing	Verified that monitoring station sends alarm notifications to the 3rd party notification system when valid software licenses for the 3rd party notification module are available on the monitoring station, and does not send alarm notifications when there are no valid software licenses. Verified that alarm notifications are sent to 3rd party notification system after software license for 3rd party notification module is activated.	Pass
AGS Performance – single central station	Verified that an alarm from an initiating source shall be delivered to the 3rd party notification system within 8 seconds.	Pass
Early Sense Settings	Verified that the Early Sense patient monitor module settings cannot be changed from the monitoring station and changes to Early Sense settings on the patient monitor are displayed on the monitoring station.	Pass
Early Sense Patient Turning	Verify that the patient turn timer and the completed turns sent from the patient monitor are received and display correctly on the monitoring station.	Pass
Early Sense Sources	Verify that Monitoring Station displays the parameter sources correctly for the Early Sense sensors.	Pass
Early Sense Exit and Motion Alarms	Verify that the Early Sense Exit and Motion alarms and values display correctly on Monitoring Station.	Pass
Early Sense Functionality Multiple Devices	Verify the Early Sense functionality when using multiple patient monitors.	Pass
Early Sense Technical Alarms	Verify that the Early Sense technical alarms display correctly on Monitoring Station.	Pass
HL7 – Configuration Settings	Verify that the Monitoring Station allows HL7 settings to be configured including which parameters are exported and the HL7 version.	Pass

Test Description	*Test Objective*	*Conclusions*
Repeater Display Visual Duplications	Verify that the Repeater Display is a visual duplication of the Central Station display.	Pass
Visual and Audible Duplications of Alarms	Verify that the Repeater Display is visual and audible duplication of the Monitoring Station display.	Pass
Graphical Trends - Parameters	Verify that Monitoring Station can display and graphically trend parameters.	Pass
Graphical Trends Display Options and Navigation	Verify that Monitor Station can display and graphically trend parameters.	Pass
Graphical Trends Review Report	Verify printing of Graphical Trends Review report.	Pass
Patient Review and 1 day Full disclosure licensing	Verify that application allows reviewing last 24 hours of vitals data on Flow sheet, Graphical trends and Continuous trends view when these licenses are activated.	Pass
Patient Review and 1 day Full disclosure licensing	Verify that when the Full disclosure, Continuous Trends, Graphical Trends and Flow Sheet view licenses are configured, the review functionalities are available.	Pass
Connex Central Station and CVSM 6000 Series Patient Monitor, with Early Sense, Directions for Use Summative Validation	Verify and validate that the Directions For Use for the Connex Central Station and CVSM 6000 series patient monitor with integration of the Early Sense Module meet usability requirements as defined in Usability Specifications (DIR 60042476 and DIR 60029496, respectively).	Pass

Test Description	*Test Objective*	*Conclusions*
Connex Central Station and CVSM 6000 Series Patient Monitor, with Early Sense, Summative Validation	The primary objective of this study is to verify and validate that Connex Central Station and CVSM 6000 Series, with Early Sense, meet their usability requirements with trained end users and that the product satisfies users' needs.	Pass

Clinical Performance Data:
No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

Device Comparison Table:
The Monitoring Station is substantially equivalent in operation and performance to the Connex Workstation (K120343).

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Device	Monitoring Station or Connex Central Station	Connex Workstation	Name change
Manufacturer	Welch Allyn, Inc.	Welch Allyn, Inc.	Same
510(k) Number	Not yet assigned	K120343	N/A
Regulation Number	870.2300 Cardiac monitor (including cardiotachmometer and rate alarm)	870.2300 Cardiac monitor (including cardiotachmometer and rate alarm)	Same
Classification code	MWI Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	MWI Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	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.	The Connex Workstation 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.	Same
Target Population	Adult and pediatric patients	Adult and pediatric patients	Same
Use Environment	Medical/Clinical	Medical/Clinical	Same

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Patients supported on one workstation	Up to 48	Up to 48	Same
Full disclosure data storage	168 hours	168 hours	Same
Central station interfaces with wireless and hardwired patient monitors over the network	Yes (Monitoring Station connects to the network by ethernet)	Yes (Connex Workstation connects to the network by ethernet)	Same
Communication with patient monitors and spot check devices: devices supported	• Episodic Devices that can communicate with the Episodic Connectivity Service (ECS) software module (tested with actual episodic devices) • Continuous monitors that can communicate with the Continuous Connectivity Service (CCS) software module (tested with actual patient monitors)	• Episodic Devices that can communicate with the Episodic Connectivity Service (ECS) software module (tested with actual episodic devices) • Continuous monitors that can communicate with the Continuous Connectivity Service (CCS) software module (tested with simulator that uses the same user interface specification used for patient monitors)	Same
Device communication protocol	WACP	WACP	Same
Adjustments made on patient monitor from central station.	Alarm limits (except Early Sense settings), Suspend (pause audio) alarms, except pausing Early Sense alarms will have no effect on the patient monitor.	Alarm limits, Suspend (pause audio) alarms.	Same, except setting adjustments for the new Early Sense patient monitor module can only be made at the bedside, not at the central station.
Supports USB kiosk for data loading from periodic devices to central station	Yes	Yes	Same

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Review capability	Yes • Patient List • Patient Details • Flow Sheet (historic episodic vital signs data and alarms for one patient in tabular format) • Continuous Trends (historic continuous and episodic vital signs data and alarms for one patient in tabular format) • Graphical Trends (historic continuous and episodic vital signs data and alarms for one patient in graphical format) • Patient Alarms history (in tabular format)	Yes • Patient List • Patient Details • Patient Review (Alarm history for one patient in tabular format)	Added new review capabilities
Software Licensing	Yes	No	Added ability to license some software features
User Configuration	Yes	No	Added user settable, password protected, software features
Informational messages	Yes (additional messages were added to support changes, like adding the ADT/EMR support, which improve users' interactions with the device)	Yes	Additional messages added to support new features and clarify information for users. These are not alarms.
Compliant with IEC 60601-1-8 alarm standard	1st edition	1st edition	Same
Supports multiple workstations	Yes	Architecture was present but feature was not implemented	Implemented ability for multiple workstations to be on the same network

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Hardcopy printing	Yes Patient List Flow Sheet Continuous Trends Graphical Trends Patient Alarms history Station Alarms history	Yes Patient List	Added ability to print additional reports
Language Support	English, French, German, Spanish	English	More languages supported
Service support tools	Yes (added service support tools such as logs, upgrade, downgrade, and configuration tools)	No	Added various service tools
Interfaces with external systems			
Ability to forward notifications and alarms to 3rd party notification systems	Yes	No	Added ability to interface with 3rd party notification systems
Admit, discharge and transfer (ADT) patients	Yes – Admit: can load patients from a list generated from the hospital's ADT system or manually; Discharge: can remove patient from Monitoring Station; Transfer: Can move a patient from one bed to another while connected to the same Monitoring Station.	Yes – Admit: can load patients manually. Does not communicate with the hospital's ADT system; Discharge: can remove patient from Connex Workstation; Transfer: Can move a patient from one bed to another while connected to the same Connex Workstation.	Added option to interface with hospital's ADT system
Optional HL7 interface capability to health information system (HIS)	CorePoint Integration Engine (OTS)	Includes architecture to support this feature in the future.	EMR support is now implemented.
Remote technical support	Yes – Partner Connect	No	Added ability to interface with Partner Connect (a separate Service software program) to provide remote support.

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Physiological Parameters Monitored			
Non-invasive blood pressure monitoring	Yes (includes display of Mean Arterial Pressure (MAP))	Yes (received MAP from patient monitor, but does not display)	Minor change to display MAP
SpHb	Yes	Yes (received SpHb from patient monitor, but does not display)	Minor change to display SpHb
SpO2 monitoring	Yes	Yes	Same
Pulse rate monitoring	Yes (from SpO2 module or Early Sense module in patient monitor)	Yes (from SpO2 module)	Additional sensor source(s) added
Temperature monitoring	Yes	Yes	Same
CO2 monitoring	Yes (includes display of FiCO2, a patient monitor-calculated value)	Yes (received FiCO2 from patient monitor, but does not display)	Minor change to display FiCO2
Respiration rate (RR) monitoring	Yes (includes display of manually entered RR, from CO2 module or Early Sense module in patient monitor)	Yes (received manually entered RR from patient monitor, but does not display)	Minor change to display manually entered RR, additional sensor source(s) added
Pain data	Yes (includes display of manually entered Pain)	Yes (received manually entered Pain data from patient monitor, but does not display)	Minor change to display manually entered Pain data
Motion	Yes (from patient monitor configured with Early Sense module)	No	Modified central station software to accommodate Early Sense data from the patient monitor*
Bed Exit	Yes (from patient monitor configured with Early Sense module)	No	Modified central station software to accommodate Early Sense data from the patient monitor*

Subject Device and Predicate Device Comparison			
Characteristic	***Subject Device***	***Predicate Device***	***Differences***
Turn Reminder	Yes (from Early Sense module in patient monitor)	No	Modified central station software to accommodate Early Sense data from the patient monitor*
Hardware and OTS Software			
Operating System	Windows 7 embedded for PC	Windows 7 embedded for PC	Same
Database	Microsoft SQL Server	Microsoft SQL Server	Same
Hardware – Computer workstation	Platform CPU Welch Allyn personal computer (some components were replaced with equivalents since they were no longer available)	Platform CPU Welch Allyn personal computer	Equivalent
Server	Standard off-the-shelf (some components were replaced with equivalents since they were no longer available)	Standard off-the-shelf	Equivalent
Hardware – Display	Size: 24" LCD Resolution: 1920x1080 2 speakers HDMI input 1 display per workstation.	Size: 22" LCD Resolution: 1680x1050 2 speakers VGA or DVI input 1 display per workstation.	Larger monitor, higher resolution, updated input connector
Keyboard/Mouse	Standard off-the-shelf (some components were replaced with equivalents since they were no longer available)	Standard off-the-shelf	Equivalent
Printers	Standard off-the-shelf	Standard off-the-shelf	Same
Supports repeater displays	Yes – supports up to 4 duplicate repeater displays	No	Added support for repeater displays

* The Early Sense Module, along with its parameters and alarms, was cleared in the Connex Vital Signs Monitor (CVSM) 6000 Series patient monitor in 510(k) K132808 on November 20, 2013.

Conclusion:

Based on the information presented in this 510(k) premarket notification, the Monitoring Station is considered substantially equivalent to (as safe, as effective and performs as well as) the currently marketed device (K120343) cited in this submission. The differences noted between the Monitoring Station and the predicate device do not impact safety or effectiveness based on the successfully conducted testing of the modified device.

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

January 31, 2014

Welch Allyn, Inc.
Kevin Crossen
Director of Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220 US

Re: K132807
Trade/Device Name: Connex Central Station (CS), model 901066 monitoring station
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II
Product Code: MWI
Dated: December 31, 2013
Received: January 2, 2014

Dear Mr. 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 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. 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 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,

Owen P. Faris -S

for

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

Enclosure

Welch Allyn®

Special 510(k) Premarket Notification
for
Connex Central Station (CS),
901066 Monitoring Station

Section 6

Indications for Use Statement

Indications for Use

510(k) Number (if known): K132807

Device Name: Connex Central Station (CS)

Indications for Use:

The Connex Central Station (CS) 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.

Prescription Use (Part 21 CFR 801 Subpart D) x 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)

Digitally signed by Owen P. Faris -S
Date: 2014.01.31 14:52:45 -05'00'