K053381

Welch Allyn

510(k) Summary

[As described in 21 CFR 807.92]

JUN 15 2006

Submitted by:

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

Contact Person:

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Date Prepared:

December 01, 2005

Trade Name:

Welch Allyn Connex™ (Vital Solutions Software)

Common Name:

Software Instrument Interface

Classification Reference:

Class II, Non-Invasive Blood Pressure Measurement System (21 CFR 870.1130, Product Code MWI)

Predicate Device:

Welch Allyn Instrument Interface Module
Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220
510(k) Number: K001265

Description of the Device:

The Welch Allyn Connex™ (Vital Solutions Software) provides for the collection and review of patient data, and also the communication of the data to information systems. It provides notifications when data deviates from ranges, allows manual entry of data, provides a means to identify and manage patients, and provides tools for enhancing productivity.

In general, Connex™ (Vital Solutions Software) shall serve as an interface between Welch Allyn medical diagnostic vitals devices and user facility information systems. It can be used either with a facility's existing information system or in the absence of an information system.

The following block diagram (figure 1) indicates the high-level interactions between the healthcare provider, patient, device, information system and Vital Solutions Software.

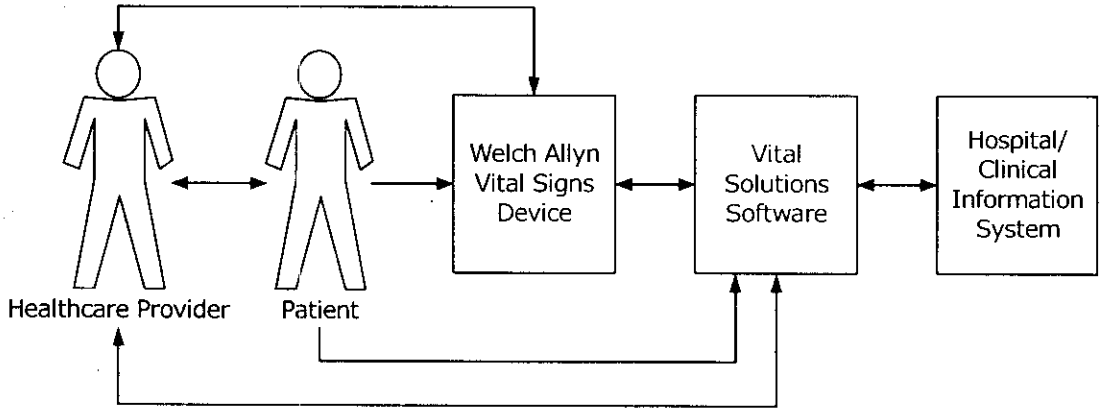

Figure 1 – Connex™ (Vital Solutions Software) Simplified Block Diagram

Intended Use:

Welch Allyn Connex™ (Vital Solutions Software) is intended for the collection and review of patient data, and also the communication of the data to information systems. It provides notifications when data deviates from ranges, allows manual entry of data, provides a means to identify and manage patients, and provides tools for enhancing productivity.

Health care providers and trained personnel are the intended users of the system.

K053381

Welch Allyn

Technological Characteristics:

The Welch Allyn Connex™ (Vital Solutions Software) is a software product. The user is the healthcare provider or administrator that gestures through a Web Browser and uses a barcode scanner and Welch Allyn medical device with the system. The Browser runs on the user's personal computer running version of Microsoft Windows operating system compatible with the Browser software and interface hardware being used.

The following table summarizes the similarities between the subject Welch Allyn Connex™ (Vital Solutions Software) and the predicate Welch Allyn Instrument Interface Module (IIM) software.

Designation	Welch Allyn Instrument Interface Module (IIM) Software 510(k) No.: K001265	Welch Allyn Connex™ (Vital Solutions Software)
Operating Principle	Software Instrument Interface	Software Instrument Interface
Operating Systems	Microsoft Windows programming language and development environment such as Visual Basic or Visual C++	Microsoft Windows operating system. • Web browser – HTML pages that also use JavaScript and Cascading Style Sheets
Intended Use	The IIM is designed to communicate with and collect data from diagnostic instruments. The data collected is then displayed for the user to verify before being sent to a computerized patient records (CPR) database where it is saved for later retrieval and review by a trained nurse or physician.	Connex™ (Vital Solutions Software) is intended for the collection and review of patient data, and also the communication of the data to information systems. It provides notifications when data deviates from ranges, allows manual entry of data, provides a means to identify and manage patients, and provides tools for enhancing productivity. Health care providers and trained personnel are the intended users of the system.
Supported Devices	Welch Allyn Electronic Diagnostic Devices	Welch Allyn Electronic Diagnostic Devices
Patient Connection	No	No
Input/Output Port	RS-232	USB, TCP/IP, RS-232
Operating Principle	Converts subset of device information parameters through device specific drivers into HL7 or DICOM format and transmits that data to any computerized patient record system.	Collects patient data from vitals devices and/or manually from user. Allows for user review of patient data and communication of patient data, via HL7, to existing information systems.

The technological differences do not affect the safety or effectiveness of the Welch Allyn Connex™ (Vital Solutions Software) device.

K053381

Summary of Effectiveness:

The Welch Allyn Connex™ (Vital Solutions Software) team has determined that the software "Level of Concern" is Moderate. (See section 10 for Connex™ software Level of Concern)

Typical concerns related to device safety are not applicable (e.g., electrical, and mechanical, biocompatibility, toxicity, corrosion, explosion, temperature, and fire hazard, EMC). However, risk management (risk, SFMEA and safety analysis) activities will be conducted in accordance with ISO 14971 Medical Devices – Application of risk management to medical devices and will comply with IEC 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems.

The Welch Allyn Connex™ (Vital Solutions Software) reads data from Welch Allyn (WA) medical diagnostic vital signs devices and does not set any ranges, tolerances, or accuracy of measurements; therefore, there are no limits and tolerances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2006

Welch Allyn, Inc.
c/o Mr. Christopher A. Klaczyk
Regulatory Affairs Manager
4341 State Street Road P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K053381
Trade/ Name: CONNEX™ Vital Solutions Software (VSS)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: June 1, 2006
Received: June 2, 2006

Dear Mr. Klaczyk:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120 (see bottom for #s). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K053381

Device Name: Welch Allyn Connex™ (Vital Solutions Software)

Indications For Use:

Welch Allyn Connex™ (Vital Solutions Software) is intended for the collection and review of patient data, and also the communication of the data to information systems. It provides notifications when data deviates from ranges, allows manual entry of data, provides a means to identify and manage patients, and provides tools for enhancing productivity.

Health care providers and trained personnel are the intended users of the system.

Prescription Use ___X___ 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053381