K052784
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Welch Allyn

NOV 2 2 2005

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:

Chris Klaczyk
Regulatory Affairs Manager

Date Prepared:

September 23, 2005

Trade Name:

Device Connectivity Software Developers Kit (SDK)

Common Name:

Software Instrument Interface

Classification Name:

Non-Invasive Blood Pressure Measurement System (21 CFR 870.1130, Product Code DXN)

Predicate Device:

Welch Allyn Vitals Software Developers Kit (SDK)
Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220
510(k) Number: K023495

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Description of the Device:

The Welch Allyn Device Connectivity Software Developers Kit (SDK) is strictly a software product.

It is designed to work with the following operating systems (Microsoft Windows 2000, XP Professional and Server 2003) and software development environments (Microsoft Visual C++ 6.0, Visual Basic 6.0, Visual Basic .NET 2003, C# .NET 2003 and Borland Delphi 8.0).

It communicates with select Welch Allyn medical devices via USB, TCP/IP and RS232 (see figure 1).

Once integrated with a third-party Computerized Patient Record (CPR), the Device Connectivity SDK will provide the CPR the ability to request and receive physiological data, device information, patient information, healthcare provider information, configuration information and error information from select Welch Allyn medical devices.

The Device Connectivity SDK will also provide an Application Programming Interface (API), communication, device errors in a human readable form, electronic help and user support information (overall description, explanation of input and outputs, online support locations and phone number).

Welch Allyn will provide a Device Connectivity Software Developer's Kit (SDK) as an OEM product licensed to 3rd party software developers, such as CPRS vendors that will enable the software developer to automate communication with and data collection from Welch Allyn's electronic medical diagnostic devices and save and store the data within the CPR's database. This Device Connectivity SDK will provide the software developers the ability to connect and capture the data through an Application Programming Interface (API).

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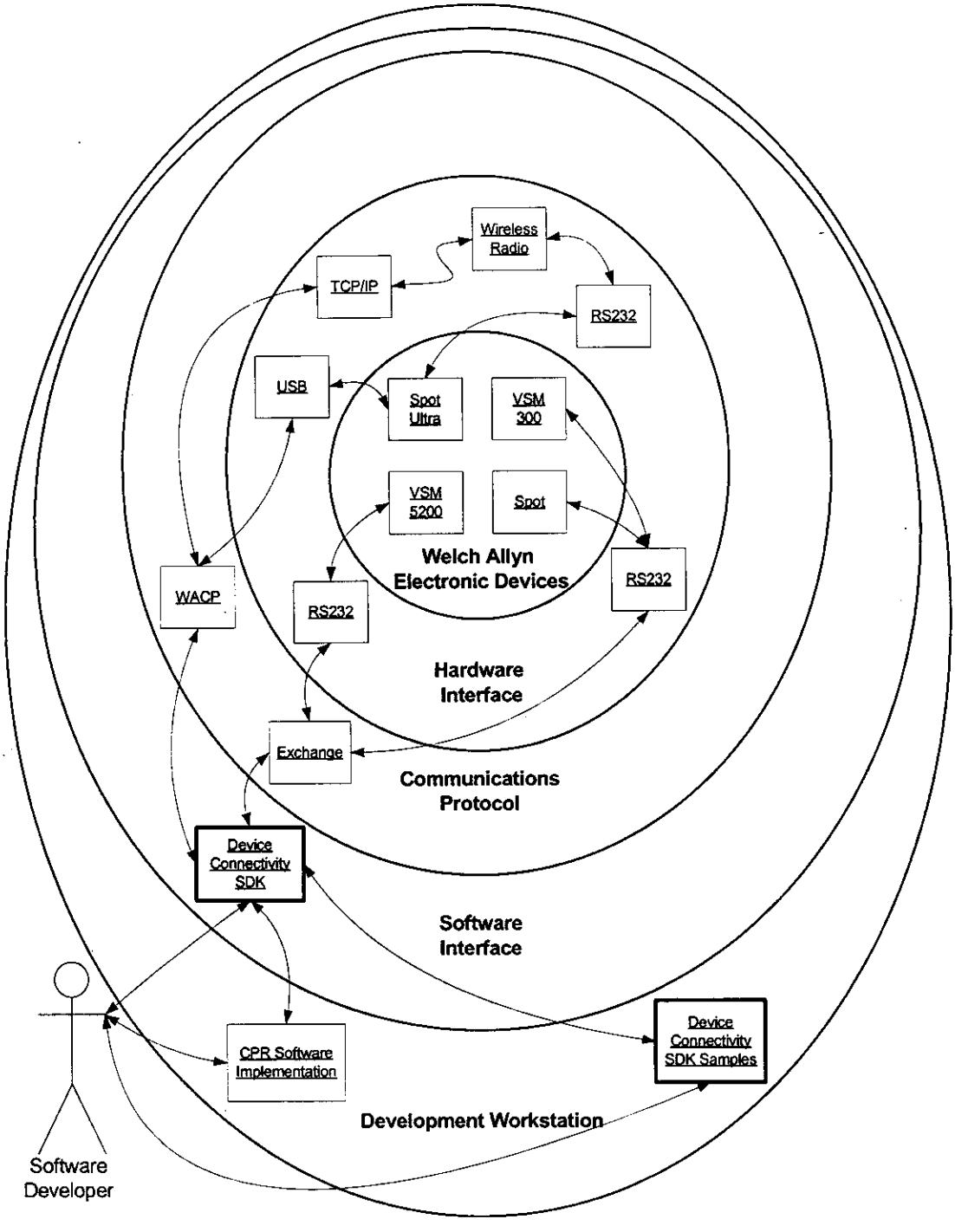

Figure 1 Device Connectivity SDK Use and Interactions Diagram

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Intended Use:

The Welch Allyn Device Connectivity Software Developers Kit (SDK) is an Original Equipment Manufacture (OEM) software product that will be integrated into software applications, such as Computerized Patient Record (CPR) systems. The Device Connectivity SDK is designed to communicate with and collect data from electronic diagnostic devices to enable an application to request, retrieve and review device data.

The Device Connectivity SDK is an enabling data communication tool and is not intended to be an end, finished product.

Technological Characteristics:

The Welch Allyn Device Connectivity Software Developers Kit (SDK) is strictly a software product. It is designed to work with Microsoft Windows operating systems using a Microsoft-based development technology (COM) similar to the Welch Allyn Vitals Software Developer's Kit (SDK).

The following table summarizes the similarities between the Welch Allyn Vitals Software SDK and the new Welch Allyn Device Connectivity SDK.

Designation	Welch Allyn Vitals Software SDK 510(k) No.: K023495	Welch Allyn Device Connectivity SDK
Operating Principle	Software Instrument Interface	Software Instrument Interface
Operating Systems	Microsoft Windows 98, NT, 2000 and XP	Microsoft Windows 2000, XP Professional, Server 2003
Intended Use	OEM software product that will be licensed to CPR manufacturers who will integrate it with and sell it as part of their CPR system. The Vitals SDK is designed to communicate with and collect data from diagnostic instruments using an instrument specific interface that is compatible with the instrument's existing communication capability. Existing instruments will not have to be changed. The data that is collected will be displayed for the user to verify before it is sent to the CPR where it is saved as part of the CPR's database.	OEM software product that will be integrated into software applications, such as CPR systems. The Device Connectivity SDK is designed to communicate with and collect data from electronic diagnostic devices to enable an application to request, retrieve and review device data. The Device Connectivity SDK is an enabling data communication tool and is not intended to be an end, finished product. The Device Connectivity SDK is intended to be used by qualified software developers.
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
Communication	Parse alphanumeric observational data, error messages	Physiologic data, device information, patient information, healthcare provider information, configuration information, error information

The technological differences do not affect the safety or effectiveness of the SDK device.

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Summary of Effectiveness:

The Device Connectivity Software Developers Kit (SDK) is a software only product and not an end product; therefore, patient safety shall not be directly compromised (minor risk). The Device Connectivity SDK is non-contact and designed to communicate with and collect data from electronic diagnostic devices to enable an application to request, retrieve and review device data.

The Device Connectivity SDK reads data from Welch Allyn (WA) electronic diagnostic devices and does not set any ranges, tolerances, or accuracy of measurements; therefore, there are no limits and tolerances.

Therefore, typical safety areas 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 Risk Management (MPD SOP-9067) & Risk Management Policy (MPD SOP-20095, using ISO 14971) and will comply with IEC 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2005

Welch Allyn, Inc.
c/o Mr. Chris Klaczyk
Regulatory Affairs Manager
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Re: K052784
Trade Name: Device Connectivity Software Developers Kit (SDK)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 30, 2005
Received: October 03, 2005

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. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

K052784

Indications for Use

510(k) Number (if known):

Device Name: Device Connectivity Software Developers Kit (SDK)

Indications For Use:

The Welch Allyn Device Connectivity Software Developer's Kit (SDK) is an Original Equipment Manufacturer (OEM) software product that will be integrated into software applications, such as Computerized Patient Record (CPR) systems. The Device Connectivity SDK is designed to communicate with and collect data from electronic diagnostic devices to enable an application to request, retrieve and review device data.

The Device Connectivity SDK is an enabling data communication tool and is not intended to be an end, finished product.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052784