OCT 31 2002

V. 510(k) Summary

[As described in CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Contact Person: David Klementowski
Corporate Regulatory Affairs Manager

Date Prepared: 18 October 2002

Proprietary Name: Welch Allyn Vitals Software Developers Kit (SDK)

Common Name: Software Instrument Interface

Classification Name: Class II 870.1130 Noninvasive Blood Pressure Measurement System

Predicate Devices: Welch Allyn Instrument Interface Module (IIM)
Welch Allyn, Inc.
510(k) Document Control Number ***K001265***

Description of the Device:

The Welch Allyn Vitals Software Developer's Kit (SDK) is strictly a software product. It is designed to work with Microsoft Window 98, NT, 2000 and XP. It communicates with the VSM 5200 series and the SPOT 4200 series medical devices via an RS232 cable in one configuration and an Infrared dongle in the other both are standard synchronous RS-232 serial interfaces.

Once integrated with a third-party computerized patient record, the SDK will provide the CPR the ability to request, receive and parse alphanumeric observational data, and error messages from these medical devices. It will provide the user with the ability to configure to a single device. It will also display information to the user, using and ActiveX display control, in a manner that is consistent with the medical device used to capture the data.

Intended Use

The Vitals Software Developer's Kit (SDK) is an Original Equipment Manufacturer (OEM) software product that will be licensed to Computerized Patient Record (CPR) manufacturers who will integrate it with and sell it as part of their CPR system. The 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 communications 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.

For access by the CPR, the data is translated from its original form into industry standard software object form (XML, Active X, COM). The SDK also provides sample program software that demonstrates how to display the data in the appropriate form.

The SDK is required for both the collection and the retrieval/review of data. The SDK will also provide the necessary set-up or configuration guidelines and help files that will allow the user to designate which instruments are connected to a personal computer (PC) at a specific location.

Safety

Due to the fact this is a software device, it is considered very safe for both practitioner and patient. The device is non-contact, its operational technique is low risk, and it only collects and displays data. The SDK is not intended to be used as a diagnostic device.

Therefore, typical safety areas are not applicable (e.g., electrical and mechanical, biocompatibility, corrosion, explosion, temperature, and fire). However, the software has undergone or will undergo the following reviews.

Risk Analysis
FMEA

Verification & Validation Tests

Summary of Effectiveness:

The determination of the Welch Allyn Vitals Software Developers Kit (SDK) effectiveness was established using:

1. Proven Windows technology and tools.
2. Specific medical devices noted under "Device Description, Intended Use, and Effectiveness".
3. Vendors who supply CPR systems to physicians and medical facilities.

The results of the testing and evaluations indicate that the Welch Allyn Vitals Software Development Kit (SDK) meets the needs and expectations of the practitioners who will be using this software device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Welch Allyn Inc.
c/o Mr. David Klementowski
Corporate Regulatory Affairs Manager
4341 State Street Road
Skaneateles Falls, NY 13153

Re: K023495
Trade Name: Welch Allyn Vitals Software Developers Kit (SDK)
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 18, 2002
Received: October 18, 2002

Dear Mr. Klementowski:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K023495

III. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn Vitals Software Developers Kit (SDK)

Indications for use:

The Vitals Software Developer's Kit (SDK) is an Original Equipment Manufacturer (OEM) software product that will be licensed to Computerized Patient Record (CPR) manufacturers who will integrate it with and sell it as part of their CPR system. The 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 communications 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.

For access by the CPR, the data is translated from its original form into industry standard software object form (XML, Active X, COM). The SDK also provides sample program software that demonstrates how to display the data in the appropriate form.

The SDK is required for both the collection and the retrieval/review of data. The SDK will also provide the necessary set-up or configuration guidelines and help files that will allow the user to designate which instruments are connected to a personal computer (PC) at a specific location.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023495