K070204/S1

Welch Allyn

Special 510(k) Premarket Notification
Link To Acuity® Clinician Notifier Option
(Modification to Acuity® Central Monitoring System)

Premarket Notification [510(k)] Summary

MAR 23 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92. Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness, is outlined below.

Date Prepared: March 5, 2007

Name of Submitter:

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107 USA

Contact:
Jeffrey W. Wagner, Director, Regulatory Affairs
Phone: (503) 530-7909
Fax: (503) 526-4901

Device Proprietary Name: Link To Acuity® Clinician Notifier
(Modification to the Acuity® Central Monitoring System)

Classification Name: System, network and communication, physiological monitors (MSX)
Detector and Alarm, Arrhythmia (DSI)

Common/Usual Names: Central monitoring system

Predicate Devices:

K052160	Acuity® Central Monitoring Station	Welch Allyn Protocol, Inc.
K052975	S/5 Pocket Viewer	Datex-Ohmeda

Device Description:

The Acuity® Central Monitoring System, in all configurations including the hardwired and wireless Acuity LT and Mobile Acuity LT System configurations, is intended to be used by clinicians for the central monitoring of neonatal, pediatric and adult patients in healthcare facilities.

In addition to the central monitoring of patient data, waveforms, and alarms and alerts, Acuity System software can include optional modules to provide extended recording and analysis of patient data. Acuity System software can include the following optional modules:

- The Full Disclosure module stores patient data for up to 96 hours (24 hours with Acuity LT and Mobile Acuity LT).

- The Arrhythmia Analysis module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The clinician is responsible for determining the clinical significance of each detected arrhythmia event or alarm. The Arrhythmia Analysis module is *not* intended for use with neonatal patients.
- The ST Analysis module provides real-time monitoring and alarms for ST segment deviations for patients with suspected heart disease and anomalies. The clinician is responsible for determining the clinical significance of each selected ST segment deviation or alarm. The ST Analysis option is *not* intended for use with neonatal patients.
- The Welch Allyn Connectivity Server (WACS) module consists of a server platform on which one or more of the following software options are installed: Link To Acuity (Acuity System patient information delivered to mobile devices running Clinician Notifier software), Web Server (Acuity System patient printout files available on Web browsers) and HL7 options.

The Link To Acuity option is Welch Allyn's mobile alarm management solution. It consists of Clinician Notifier software for non-proprietary mobile devices and administrative software for the Welch Allyn Connectivity Server (WACS).

Mobile devices running the Clinician Notifier software deliver patient alarm information and real-time waveforms gathered from patient monitors connected to the Acuity Central Monitoring System. The devices are not intended for use as primary alarm notification devices. Devices running Clinician Notifier software are not directly connected to patients.

The Link To Acuity option is designed to extend the patient monitoring functions of the Acuity Central Monitoring System. The software enables administrators to track the status of clinician-patient assignments, and it enables clinicians to track, respond to and view Acuity System patient alarms, view historical alarm details and waveforms, and view real-time patient waveforms. The mobile devices can be used for barcode scanning to enter patient ID and room number.

The Link To Acuity option is to be used by authorized health care professionals using standard institutional procedures and good clinical practice guidelines for patient monitoring. Staff training in the operation of the Link To Acuity option is essential for optimal use. Users should be skilled at the level of a technician, nurse, physician, health care provider or medical specialist, with the knowledge and experience to acquire and interpret patients' vital signs data.

Individuals using the Link To Acuity option should be familiar with its operation as described in the directions for use manual, and they should understand all warnings and cautions in the directions for use manual.

Technological Characteristics:

The Welch Allyn Link To Acuity Clinician Notifier option allows for alarm management remote from the central monitoring station. Through a network of wireless and/or hardwired devices connected to the Welch Allyn Acuity Central Monitoring System, alarms, real time data, and other information can be viewed from a generic mobile computer configured with Welch Allyn Link To Acuity Clinician Notifier option software. The Welch Allyn Link To Acuity Clinician Notifier is to be used as a supplement to other patient monitoring and not as a primary alarm notification device.

Link To Acuity® Clinician Notifier Features

View Patient Info
Status of all patients in unit
History of alarms
Real-time waveform
List of current alarms
Details of an alarm

Respond to Alarms and Alerts
Patient alarms delivered to Clinician Notifier devices
Two possible alarm delivery modes – Escalation and Broadcast
Alarm notifications
Respond to patient alarms

Security
Login
Logout

Patient Assignment
Assign patients to clinicians
Enter and confirm a patient's ID

Performance Data:

The subject device has been tested in accordance with the following Welch Allyn documents using production equivalent units prior to market release.

830-1423-00	Test Plan, Acuity V7.00
831-1285-00	Pre-Validation Clinical Entry Test Report Clinician Notifier 2.35/WACS 2.10.00
830-1472-00	Welch Allyn Link to Acuity® – Simulated Clinical Engineering Test Protocol
831-1248-00	Link To Acuity® Simulated Clinical Testing Report

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Welch Allyn Protocol's product development procedure. Welch Allyn Protocol's Quality System conforms to 21 CFR 820 and is certified to ISO 13485:2003.

Conclusion:

Based on the information contained in this submission, Welch Allyn Protocol, Inc. believes that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2007

Welch Allyn Protocol, Inc.
c/o Mr. Jeffrey Wagner
Director, Regulatory Affairs
8500 SW Creekside Place
Beaverton, OR 97008

Re: K070204
Trade/Device Name: Link to Acuity Clinical Notifier
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: March 12, 2007
Received: March 13, 2007

Dear Mr. Wagner:

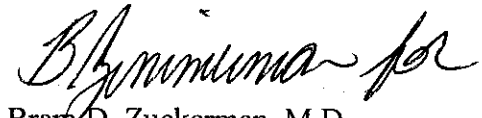
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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

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Statement of Indications for Use

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Applicant:

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

510(k) Number: K070204

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 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 K070204