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Welch Allyn

DEC 16 2005

510(k) Summary

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: July 27, 2005

Name of Submitter:

John E. Sawyer
Director, World Wide Regulatory Affairs
Welch Allyn, Inc
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Device Proprietary Name: Acuity® Central Monitoring Station

Classification Name: Arrhythmia Detector and Alarm (Including ST Segment and Alarm)

Common/Usual Names: Arrhythmia Detector and Alarm

Predicate Device: The subject device has the same indications for use as the predicates.

K022453	Acuity® Central Monitoring System	Welch Allyn Protocol, Inc.
K972121	Acuity Central Station	Protocol Systems, Inc.
K935846	Model Acuity Central Station	Protocol Systems, Inc.

Device Description:

Acuity® Central Monitoring Station
Product Code: DSI and MLD
CFR Section: 870.1025

The Acuity® Central Monitoring Station is Welch Allyn's Central Monitoring solution. It consists of the Acuity® Central Monitoring Station, the Acuity software and a collection of other commercially available networking hardware products. The system connects to a network of patient monitors to record and analyze the data being acquired by those devices. This solution offers a proven technology with the options and features needed to support a distributed network of connected devices while providing arrhythmia detection and alarms for adult and pediatric patients.

The Acuity system supports patient information management, patient alert and alarm management, patient data review, system administration and product installation and service. It leverages various networking and connectivity options to obtain and distribute information where and when needed.

Acuity is available in multiple product configurations. Acuity systems can be ordered off-the-

shelf or custom configured to meet a customer's unique needs based on hospital policy, healthcare facility size, patient census and floor layout. In all cases, the user must carefully review the features and functionality of both the distributed devices and the Acuity® Central Monitoring Station to ensure that clinical needs are met.

The Acuity® Central Monitoring Station is not directly connected to patients. It is designed to be used as a central monitoring system for a set of patient monitors supporting both continuously and intermittently acquired data. The monitors supported include, but are not limited to, the following Welch Allyn devices: Propaq CS, Propaq LT and Micropaq as configured to interface with Acuity.

Acuity systems monitor patient data supplied by a bedside monitor and do further processing of that data by software at the Acuity® Central Monitoring Station. Acuity systems with the arrhythmia option calculate heart rate using multiple ECG leads and arrhythmia analysis algorithms, where the bedside monitor uses a heart rate algorithm based on data from a single ECG lead. The overall performance of the networked system is based upon trending and data management techniques consistent with industry practice and applicable standards.

It is important to note that some Acuity software options and/or devices will support adult and pediatric patients, but are not intended for neonatal patients. Specifically, the ST Analysis and Arrhythmia Analysis software options are intended only for adult and pediatric patients.

Acuity® Central Monitoring Stations and distributed monitoring devices are prescription devices to be used as authorized by health care professionals and/or by institutional standard procedures and good clinical practice guidelines for monitoring of specific patients. Staff trained in the operation of Acuity and the patient monitoring devices connected to it is essential for optimal use. System users should be skilled at the level of a technician, nurse, physician, healthcare provider or medical specialist.

Indications For Use

The Acuity® Central Monitoring 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, waveforms, alarms and alerts, the Acuity software can include optional modules to provide extended recording of patient data (Full Disclosure), arrhythmia monitoring and ST analysis.

- Full Disclosure stores patient data for up to 96 hours.
- Arrhythmia monitoring 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 module is not intended for use with neonatal patients.
- ST analysis module provides real-time monitoring and alarms for ST segment deviations, from a reference beat, 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 module is not intended for use with neonatal patients.

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Technological Comparison to Predicate Devices:

	Subject	Predicate	Predicate
Manufacturer	Welch Allyn Protocol	Welch Allyn Protocol	Protocol Systems
510(k) Number	Pending	K022453	K935846 / K972121
Device Name	Acuity® Central Monitoring Station	Modification to Acuity Central Monitoring System	Acuity Central Station
Classification Code	Pending	DSI	MLD
Patient Population	Neonate, Pediatric, Adult No arrhythmia support or ST analysis for neonate	Neonate, Pediatric, Adult No arrhythmia support or ST analysis for neonate	Neonate, Pediatric, Adult No arrhythmia support or ST analysis for neonate
Use Environment	Medical/Clinical	Medical/Clinical	Medical/Clinical
Analog or Digital	Digital	Digital	Digital
Electrode Configuration	3 or 5 wire: 7 vector display	3 or 5 wire: 7 vector display	3 or 5 wire: 7 vector display
Frequency Response	Not Used	Not Used	Not Used
Input Impedance	Not Used	Not Used	Not Used
Dynamic Range	Not Used	Not Used	Not Used
Common Mode Rejection Rate (CMMR)	Not Used	Not Used	Not Used
QRS Detection Sensitivity	AHA 99.87 MIT 99.95	AHA 99.88 MIT 99.93	AHA 99.18 MIT 99.51
Pacemaker Pulse Rejection	Not Used	Not Used	Not Used
System Noise	Arrhythmia Noise Detection	Arrhythmia Noise Detection	Arrhythmia Noise Detection
Hard-wired and/or Wireless	Both	Both	Both
Radio Frequency Telemetry	Wireless 802.11 support	Wireless 802.11 support	455 to 465 MHz
Transtelephonic and/or Fax Capability	Technical Support Remote Dial Up	Technical Support Remote Dial Up	Technical Support Remote Dial Up
Alarm Levels/Mgmt. Standalone	Vital Signs, Arrhythmia, and ST Analysis	Vital Signs, Arrhythmia, and ST Analysis	Vital Signs, Arrhythmia, and ST Analysis
Alarm Levels/Mgmt. Connected/Linked	Vital Signs, Arrhythmia, and ST Analysis	Vital Signs, Arrhythmia, and ST Analysis	Vital Signs, Arrhythmia, and ST Analysis
Data Storage	96 hour Full Disclosure	96 hour Full Disclosure	96 hour Full Disclosure
Samples per second – Bit Resolution	180 samples/sec for display 500 samples/sec for arrhythmia	180 samples/sec for display 500 samples/sec for arrhythmia	180 samples/sec for display 500 samples/sec for arrhythmia

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Performance Data:

	AHA	MIT
QRS Sensitivity	99.86	99.95
QRS Positive Predictivity	99.89	99.88
Ventricular Sensitivity	93.26	95.52
Ventricular Positive Predictivity	98.21	97.07

Conclusions:

The Acuity® Central Monitoring Station is as safe, as effective and performs as well as the legally marketed devices predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Welch Allyn, Inc.
c/o Mr. John E. Sawyer
Vice President, World Wide Regulatory Affairs
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Re: K052160
Trade Name: Acuity® Central Monitoring Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: November 08, 2005
Received: November 15, 2005

Dear Mr. Sawyer:

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

1 Statement of Indications for Use

510(k) Number (if known): K052160

Device Name: Acuity® Central Monitoring Station

Indications for Use:

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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 K052160