



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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April 22, 2016

Global Instrumentation, LLC  
Craig Sellers  
Regulatory Affairs Manager  
8104 Cazenovia Road  
Manlius, New York 13104

Re: K152701

Trade/Device Name: Matrix Mini ECG Monitor

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)

Regulatory Class: Class II

Product Code: DSI, DRT, BZQ

Dated: March 14, 2016

Received: March 17, 2016

Dear Craig Sellers:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

## Indications for Use

510(k) Number (if known)  
K152701

Device Name  
Matrix Mini ECG Monitor

### Indications for Use (Describe)

The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and alternate professional healthcare environments. The system is indicated for use in pediatric and adult patients.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

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### **510(k) Summary**

[As described in 21 CFR 807.92]

**Submitted by:** Global Instrumentation LLC.  
8104 Cazenovia Road  
Manlius, NY 13104 USA

**Contact Person:** Craig Sellers  
Regulatory Affairs Manager  
Phone: (315) 682-0272 Ext. 120  
Fax: (315) 685-0278  
E-mail: [craigs@globalinstrumentation.com](mailto:craigs@globalinstrumentation.com)

**Date Prepared:** March 14, 2016

**Trade Name:** Matrix Mini ECG Monitor

**Common Name:** Cardiac monitor  
(including Cardiometer and rate alarm)

**Classification Reference:** Class II, 870.3247 Cttj { v j o k F gvevt "cpf "Crto (including  
ST segment Measurement and alarm)  
Classification Product Code – DUK  
Subsequent Product Codes – DTV, BZQ

**Predicate Devices:**

**Atlas Monitor**  
(Primary Predicate Device)  
Cardiac monitor (including Cardiometer and rate alarm)  
Product Code – DRT (Atlas also includes BZQ function)  
Welch Allyn, Inc.  
510(k) Number K984033

**Acuity Central Monitoring Station**  
(Supplemental Predicate Device)  
Arrhythmia Detector and Alarm (including ST-segment  
measurement and alarm)  
Product Code – DSI  
Welch Allyn, Inc.  
510(k) Number K120774

## 510(k) Summary

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### **Description of the Device:**

The Matrix Mini ECG Monitor system provides a cardiac monitor which monitors ECG derived heart rate, ECG electrode impedance respiration rate, and specific ECG arrhythmias (including asystole, ventricular tachycardia, and ventricular fibrillation). The Matrix Mini ECG Monitor system consists of a display module, a data acquisition module and an ECG patient cable.

The display module and the data acquisition module are connected together with a USB interface. The data acquisition module is connected to the patient with the ECG patient cable, which is attached to standard ECG electrodes applied to the patient's skin surface.

The display module consists of a tablet computer which provides the graphical display, user interface, data processing, data reporting/review, data communication, alarm, and data storage functions. The data acquisition module provides the patient electrical isolation, interface to ECG skin surface electrodes attached to patient, conversion of analog ECG electrode data to digital data, data processing, and data communication functions. An accessory ECG patient cable is provided to connect the data acquisitions module to standard skin surface ECG electrodes. The accessory ECG patient cables are available in 3 or 5 ECG lead configurations.

The Matrix Mini ECG Monitor provides an ECG heart rate monitor that includes software capable of limited ECG analysis and ECG electrode impedance respiration rate measurement. The Matrix Mini ECG monitor includes the basic functions of the 3 or 5 lead ECG monitoring system hardware standard to a Cardiac Monitor including a Cardiotachometer and rate alarm (product code DRT). The primary predicate device is a cardiac monitor and has a product code of DRT and also provides functions for ECG electrode impedance respiration rate measurement (product code BZQ).

The Matrix Mini ECG Monitor device software can report asystole, ventricular tachycardia and ventricular fibrillation, which may be thought of as arrhythmias, we selected a supplemental predicate device (K120774) with the product code DSI. Both the software device component and hardware components are presented below compared to the currently marketed predicate devices.

The Matrix Mini ECG Monitor uses software to process and display the ECG electrode derived cardiac information to the user. The analog ECG electrode data is acquired and converted to digital data using conventional, well proven, and widely used, electronic digital data acquisition technology. The technology has operational and performance characteristics that comply with IEC 60601-2-27:2011, "Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment". The asystole, ventricular tachycardia and ventricular fibrillation algorithms use conventional software ECG analysis techniques and have been evaluated using ANSI/AAMI EC57:2012 "Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms"

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The Matrix Mini monitoring device is a prescription device to be used by authorized health care professionals using standard institutional procedures and standards of care for patient monitoring. Staff training in the operation of the Matrix Mini ECG Monitor device 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' ECG data. Individuals using the Matrix Mini ECG Monitor should be familiar with its operation as described in the manual, and they should understand all warnings and cautions in the manual.

### **Shelf Life**

The product does not have a shelf life. A shelf-life is not applicable because of low likelihood of time-dependent product degradation. The device uses technologies, components and materials that do not significantly change in characteristics with time when used/stored in the specified operating and storage conditions. The materials and technologies utilized ensure that the specified storage, and usage, conditions are not expected to affect device safety or effectiveness

### **Indications for Use:**

The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare facilities. The system is indicated for use in pediatric and adult patients.

### **Predicate Device Selection**

The primary predicate device selected is the Atlas Monitor (Welch Allyn, K984033, Product Code DRT). The Atlas device also provide provides the function of ECG electrode impedance respiration rate measurement (product code BZQ). A supplemental predicate device selected is the Acuity Central Monitoring Station Monitor (Welch Allyn, K120774, Product Code DSI). The Acuity device includes detection and alarming for asystole, ventricular tachycardia, and ventricular fibrillation arrhythmias. These devices are presently in commercial distribution globally including the United States of America. The Matrix Mini ECG Monitor has similar technological characteristics, indications for use, and performance characteristics as the predicate devices. The Matrix Mini ECG Monitor is similar in design, function and application to the predicate device. All materials and technologies are currently utilized in in other medical devices therefore, no new issues of safety or effectiveness are introduced by using this device.

### **Technological Characteristics:**

The Matrix Mini ECG Monitor (System) uses conventional electronic digital data acquisition techniques to digitize and process ECG signals from skin surface ECG electrodes attached to a patient. The System consists of the Matrix Mini Display Module and the Matrix Mini Acquisition Module which are connected by an electrically isolated USB communication interface. The display module provides the data/waveform display and the user interface functions of the system. The acquisition module acquires the ECG signal from ECG electrodes on the surface of the patient's skin and provides the electrical isolation required to ensure patient safety. Refer to Table 1 at the end of this document for a detailed comparison

## 510(k) Summary

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of the subject device to the predicate device.

The Matrix Mini ECG monitor uses software to process the ECG electrical signals and display the ECG and respiration information to the user. The technology has operational and performance characteristics that comply with IEC 60601-2-27:2011, “Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment” The asystole, ventricular tachycardia and ventricular fibrillation algorithms use conventional software ECG analysis techniques and have been evaluated using ANSI/AAMI EC57:2012 “Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms”

The Matrix Mini ECG Monitor uses the same technologies as the predicate devices. The Matrix Mini ECG Monitor is technically equivalent to the Atlas Monitor (K984033) and the Acuity Central Monitoring Station (K120774) with respect to technical and performance characteristic including, data storage, patient management, data review, measured physiological parameters and alarm management.

### **Non-Clinical Tests:**

Verification and validation testing was conducted to ensure expected performance of the Matrix Mini ECG Monitor

The Matrix Mini ECG Monitor was also tested to evaluate its safety and effectiveness based on the following standards and guidance documents:

- IEC 60601-2-27 Edition 3.0 2011-03 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]
- ISO 14971: 2007 - Medical devices - Application of risk management to medical devices
- IEC 62304: 2015 - Medical device software - Software life cycle processes
- ANSI/AAMI EC57:2012 - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- ANSI AAMI EC53:2013 - ECG trunk cables and patient leadwires
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- IEC 60601-1-8 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- FDA guidance Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (October 28, 2003), was utilized in the planning and conduct of all performance testing.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The device's software has been validated in accordance with this guidance.

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The Matrix Mini ECG Monitor system has been tested and found to be in compliance with the applicable recognized safety, performance and electromagnetic compatibility standards. The standards used are consistent with the standards and testing used for the predicate devices. The results of the testing demonstrate that the device is as safe, as effective, and performs as well as, or better than, the predicates.

### **Clinical Performance Data:**

No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

### **Conclusion:**

Based on the information presented in this 510(k) premarket notification, the Global Instrumentation LLC Matrix Mini ECG Monitor is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed devices cited in this submission.

## 510(k) Summary

### TABLE 1

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
<b>Device Name</b>	Atlas Monitor (primary predicate device)	Matrix Mini ECG Monitor	N/A
<b>Manufacturer</b>	Welch Allyn, Inc.,	Global Instrumentation, LLC.	N/A
<b>510(k) Number</b>	K984033	N/A	N/A
<b>Product Code</b>	DRT	DRT, DSI, BZQ	Same
<b>Regulation Name</b>	870.2300 Cardiac monitor (including Cardiotachometer and rate alarm)	870.2300 Cardiac monitor (including Cardiotachometer and rate alarm)	Same
<b>Indications for Use</b>	<p>The indications for use for the Atlas Monitor, include the monitoring of the following human physiological vital signs: Blood Oxygenation (SpO2) measurement, ECG waveform derived from 3 or 5 lead measurement, Respiration rate/waveform derived from ECG or CO2, Temperature measurement via YSI 400 series probes, Noninvasive Blood Pressure (NIBP) measurement, CO2, End tidal side stream/waveform (ETCO2), Heart Rate derived from selected source (ECG, SpO2).</p> <p>The target populations are adult and pediatric populations. The monitor is intended for use within the healthcare facility setting.</p>	<p>The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate, and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare environments. The system is indicated for use in pediatric and adult patients.</p>	<p style="text-align: center;">Similar</p> <p>The Matrix Mini ECG Monitor is equivalent to the Atlas Monitor (K984033) in ECG, Respiration and heart rate parameter performance. The target populations are the same.</p> <p>Some functions are removed since the subject device is only for heart rate, respiration rate, and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation</p> <p>The Matrix Mini ECG arrhythmia analysis is limited to cardiac standstill (asystole), ventricular tachycardia and ventricular</p>

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
			fibrillation. This is equivalent to primary predicate in conjunction with Welch Allyn Acuity Central Monitoring Station (K120774).
<b>Target Population</b>	Adult and pediatric populations	Pediatric and adult patients of any gender.	Same
<b>Where Used</b>	The monitor is intended for use within the healthcare facility setting.	The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and professional healthcare environments.	Similar – more detail added to description.
<b>Design</b>	Multiparameter device used to monitor human physiological vital signs.	Multiparameter device used to monitor ECG and respiration human physiological vital signs.	<p>Similar</p> <p>Matrix Mini ECG monitor provides the same functions for ECG, heart rate, and respiration parameters derived from ECG electrodes.</p> <p>Matrix Mini does not provide monitoring for temperature, SpO2, CO2, NIBP or ETCO2.</p> <p>The Matrix Mini provides the same ECG, heart rate, and respiration parameters that is provided by the predicate devices. For ECG and respiration parameters, the Matrix Mini is equivalent to the predicate devices.</p>
<b>Technologies</b>	ECG and ECG respiration sensing with conventional patient skin surface applied electrodes. ECG/Respiration data	ECG and ECG respiration sensing with conventional patient skin surface applied electrodes. ECG/Respiration data	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
	acquisition performed with solid state amplifiers, analog to digital converter and processing of data controlled by microprocessor/microcontroller. Data is converted from analog to digital format and digital data is then processed and analyzed. Microcontroller based system provides electronic user interface with alarm functions, electronic waveform displays and numeric data display. Internal battery power supply. External AC power supply/battery charging.	acquisition performed with solid state amplifiers, analog to digital converter and processing of data controlled by microprocessor/microcontroller. Data is converted from analog to digital format and digital data is then processed and analyzed. Microcontroller based system provides electronic user interface with alarm functions, electronic waveform displays and numeric data display. Internal battery power supply. External AC power supply/battery charging.	
<b>Heart Rate Range</b>	21 to 249 beats/minute	20 to 300 beats/minute	Similar  Matrix Mini detects wider range of heart rates. This will provide performance that is equal to, or better than, that of the predicate devices.
<b>Heart Rate Accuracy</b>	$\pm 3$ beats/minute or $\pm 3\%$ whichever is greater	$\pm 3$ beats/minute or $\pm 3\%$ whichever is greater	Same
<b>Bandwidth, Normal Mode</b>	0.5 to 40 Hz	0.05 to 70 Hz	Similar  Matrix Mini has wider range of frequency response bandwidth. This will provide performance that is equal to, or better than, that of the predicate devices.
<b>Leads</b>	3 wire or 5 wire, available in AHA or IEC colors	3 wire or 5 wire, available in AHA or IEC colors	Same
<b>Electrodes</b>	Disposable snap electrodes applied to patient skin surface.	Disposable snap electrodes applied to	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
		patient skin surface.	
<b>Gain</b>	10 mm/mV, adjustable, visual scale indicator	10 mm/mV, adjustable, visual scale indicator	Same
<b>Lead Display</b>	Single, user selectable: I, II, III, V	Single, user selectable: I, II, III, V	Same
<b>Heart Rate Display</b>	Numeric	Numeric	Same
<b>Waveform Display</b>	One row minimum of ECG waveform display	One row minimum of ECG waveform display	Same
<b>Leads Off Condition</b>	Detected and displayed (selected lead only)	Detected and displayed (selected lead only)	Same
<b>Heart Rate Alarms</b>	High and Low Heart Rate	High and Low Heart Rate	Same
<b>Alarm Ranges</b>	Heart Rate Low Limits: 21 to 245 beats/minute Heart Rate High Limits: 25 to 249 beats/minute	Heart Rate Low Limits: 20 to 300 beats/minute Heart Rate High Limits: 20 to 300 beats/minute	Similar  Matrix Mini supports a wider range of alarm limits. This ensures performance in this area is equal to, or better than, that of the predicate devices.
<b>Data Acquisition Technique</b>	Analog to Digital Convertor	Analog to Digital Convertor	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
<b>Samples per second (sample rate)</b>	180 samples/sec	250 samples/sec	Similar  Matrix Mini has higher sampling rate. This will provide data quality that is equal to, or better than, that of the predicate devices.
<b>Input Impedance</b>	>2.5 Megohms at 10Hz	>2.5 Megohms at 10Hz	Same
<b>Input Protection</b>	Defibrillator and Electrosurgery protected	Defibrillator and Electrosurgery protected	Same
<b>Defibrillator Recovery per EC13:1992 Clause 3.1.2.1a)</b>	Yes	Yes	Same
<b>Pacemaker Display</b>	Pacemaker signals displayed as captured.	Pacemaker signals displayed as captured.	Same
<b>Pacemaker Detection</b>	Yes	Yes	Same
<b>Pacemaker Reject</b>	Yes	Yes	Same
<b>Lead Off Detection</b>	Yes	Yes	Same
<b>ECG Respiration/Lead Off Detection Current</b>	50nA max for RA, LA, LL, V; 200nA max for RL	50nA max for RA, LA, LL, V; 200nA max for RL	Same
<b>ECG Respiration Measurement Technique</b>	Trans-thoracic impedance	Trans-thoracic impedance	Same
<b>ECG Respiration # Leads</b>	Single	Single	Same
<b>ECG Respiration Range</b>	5 to 100 breaths/minute	5 to 100 breaths/minute	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
<b>ECG Respiration Accuracy</b>	±3 breaths/minute	±2 breaths/minute	Similar  Matrix Mini has better accuracy. This ensures performance in this area is equal to, or better than, that of the predicate devices.
<b>Respiration Alarms</b>	High and Low Respiration Rate	High and Low Respiration Rate	Same
<b>Respiration Alarm Ranges</b>	Respiration Low limits: 5 to 100 breaths/minute Respiration High limits: 5 to 100 breaths/minute	Respiration Low limits: 5 to 100 breaths/minute Respiration High limits: 5 to 100 breaths/minute	Same
<b>Respiration Rate Display</b>	Numeric	Numeric	Same
<b>ECG analysis and detection of limited arrhythmias similar to Acuity (K120774 supplemental predicate) in conjunction with the Atlas Monitor (K984033 primary predicate). The below provides the comparison to K120774.</b>			
<b>Device Name</b>	Acuity Central Monitoring Station (supplemental predicate device)	Matrix Mini ECG Monitor	N/A

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
<b>Manufacturer</b>	Welch Allyn, Inc.,	Global Instrumentation, LLC.	N/A
<b>510(k) Number</b>	K120774	N/A	N/A
<b>Product Code</b>	DSI	DRT, DSI, BZQ	Similar, Acuity and Matrix Mini both include DSI product code.
<b>Regulation Name</b>	870.1025, Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)	870.2300 Cardiac monitor (including Cardiometer and rate alarm)	Acuity and Matrix Mini ECG Monitor both provide ECG analysis and detection of waveforms to detect the following arrhythmia: asystole, ventricular tachycardia, and ventricular fibrillation.
<b>Indications for Use</b>	<p>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.</p> <p>In addition to the central monitoring of patient data, waveforms, alarms and alerts,</p> <p>The Acuity software can include operational modules to provide extended recording of patient data (Full Disclosure), arrhythmia monitoring and ST analysis.</p> <p>* Full disclosure stores patient data for up to 96 hours</p> <p>* Arrhythmia monitoring module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The</p>	<p>The Matrix Mini ECG Monitor is intended for continuous measurement of heart rate, respiration rate, and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare environments.</p> <p>The system is indicated for use in pediatric and adult patients.</p>	<p>Similar</p> <p>The Matrix Mini ECG Monitor is equivalent to the Atlas Monitor in ECG, Respiration and heart rate parameter performance.</p> <p>The target populations are the same.</p> <p>Some functions removed since the subject device is only for ECG.</p> <p>The Matrix Mini ECG Monitor includes arrhythmia analysis that is limited to cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation. This is equivalent to the Atlas primary predicate (K984033) in conjunction with the arrhythmia monitoring</p>

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
	<p>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.</p> <p>* 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.</p> <p>The ST analysis module is not intended for use with neonatal patients.</p>		<p>module functions of the Welch Allyn Acuity Central Monitoring Station. (K120774)</p>
<b>Target Population</b>	<p>Adult and pediatric populations (for the arrhythmia module) which provides the asystole, ventricular tachycardia and ventricular fibrillation arrhythmia analysis.</p>	<p>Pediatric and adult patients of any gender.</p>	<p>Same</p> <p>The arrhythmia module of the Allyn Acuity Central Monitoring Station is intended for pediatric and adult patients. The arrhythmia module of is not intended for use with neonatal patients.</p>
<b>Where Used</b>	<p>The product is intended for use within healthcare facilities.</p>	<p>The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and professional healthcare environments.</p>	<p>Similar – more detail added to description for Matrix Mini. No significant difference between Matrix Mini and predicate devices. All devices are intended for use</p>

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
			within healthcare facilities.
<b>Design</b>	Multiparameter device used to monitor human physiological vital signs including detection of ECG Arrhythmias including asystole, ventricular tachycardia, and ventricular fibrillation.	Multiparameter device used to monitor ECG and respiration human physiological vital signs.	<p>Similar</p> <p>Matrix Mini does not provide monitoring for temperature, SpO2, CO2, NIBP or ETCO2.</p> <p>The Matrix Mini ECG monitor does not perform ST analysis.</p> <p>Matrix Mini ECG monitor has the same design functions as the predicate devices for ECG, heart rate, and respiration parameters derived from ECG electrodes, including detection of asystole, ventricular tachycardia, and ventricular fibrillation.</p>
<b>Technologies</b>	Uses software running on computer hardware to monitor and analyze digital patient physiological data. Uses personal computer technologies to provide user interface to system. Supports optional network and printer connections.	Uses software running on computer hardware to monitor and analyze digital patient physiological data. Uses personal computer technologies to provide user interface to system. Supports optional network and printer connections.	Same
<b>Heart Rate Arrhythmia detection</b>	Asystole, Ventricular tachycardia and Ventricular Fibrillation	Asystole, Ventricular tachycardia and Ventricular Fibrillation	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
<b>ST analysis</b>	Yes	No	ST analysis is not required by Matrix Mini ECG monitor indications for use.  Matrix Mini ECG Monitor arrhythmia detection limited to asystole, ventricular tachycardia and ventricular fibrillation.
<b>Alarms</b>	Can configure, observe, and respond to an alarm condition.	Can configure, observe, and respond to an alarm condition.	Same
<b>Heart Rate Arrhythmia alarm settings</b>	Yes	Yes	Same
<b>Alarm review</b>	Yes	Yes	Same
<b>Waveform display</b>	Yes – ECG waveforms	Yes – ECG waveforms	Same
<b>Patient Data Source</b>	Central station interfaces with wireless and hardwired patient monitors for patient data	Matrix Mini ECG Monitor is a hardwired patient monitor for patient data. Connects directly to patient.	Similar  The Matrix Mini ECG monitor provides for monitoring of the patient at the patient location using a hardwired interface. The Matrix Mini ECG monitor does not provide for remote monitoring of the patient.  The Matrix Mini ECG monitor provides all required information at the patient location.
<b>Logs</b>	Waveform and Error logs	Waveform and Error logs	Same
<b>Logging capability</b>	Yes-logs a variety of information including alarms, alerts, connection and	Yes-logs a variety of information including alarms, alerts, connection and	Same

## 510(k) Summary

<i>Characteristic</i>	<i>Predicate Devices</i>	<i>Subject Device</i>	<i>Differences</i>
	disconnection of monitors, significant actions by clinicians, etc. Logs provide an audit trail for system failures and customer complaints. System can be set to capture more information for troubleshooting.	disconnection of monitors, significant actions by clinicians, etc. Logs provide an audit trail for system failures and customer complaints. System can be set to capture more information for troubleshooting.	
<b>Full disclosure data storage</b>	Up to 96 hours available to customers	Up to 96 hours available to customers	Same
<b>Data interfaces to patient data acquisition device</b>	RS232 and optional network connections	USB	Similar  The Matrix Mini ECG monitor does not support use of wireless or remote monitoring of the patient. The Matrix Mini uses a hard wired serial data interface (USB) which is as reliable, or more reliable, than the data interfaces used by the predicate devices. The subject device performance in this area is as good as, or better than, that of the predicate device.
<b>Optional data interfaces</b>	Optional network connections to external devices such as printers.	Optional network connections to external devices such as printers.	Same