1.0 Description of Device
The HRV Acquire (HRV) Device with TestWorks software can be used as a standalone cardiovagal device to support heart rate variability testing and expiratory pressure evaluation during valsalva breathing testing. The HRV device supports measurement of heart rate variability, respiratory effort from commercially available circumferential chest bellows, display of a valsalva breathing metronome breathing cue and display of non-invasive beat to beat blood pressure from an external device. An example of an external blood pressure device is the commercially available FMS Finometer, cleared to market by 510(k) K880572. Other commercially available, FDA cleared to market external beat to beat blood pressure devices with an analog blood pressure signal output may be applied.

The HRV device user interface is integrated into the existing WR Medical Electronics CO TestWorks software. The Test Works software was cleared to market with the Q-Sweat device, 510(K) K992874. The TestWorks software is modified to support an interface to the HRV device.

The HRV device may be mounted to a standard IV Pole.

The HRV device has two modes of operation:
1) Valsalva Mode supporting valsalva breathing cue to the subject under test,
2) Heart Rate Deep Breathing (HRDB) Mode.
In both modes, the HRV device acquires and the TestWorks software displays heart rate and blood pressure. The HRV device eliminates the need for a separate ECG acquisition device when these types of studies are performed. The HRV device acquires a Lead II ECG signal.
The HRV device and TestWorks software do not supply any alarms. All interpretation of acquired and displayed data is the responsibility of the physician/clinician supervising the test.

1.1 Variations and Accessories
There are no variations of HRV device.

2.0 Intended use of Device
The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers:
- Expiratory pressure recording and display
- Respiratory effort
- Breathing cue metronome
- Heart rate via electrocardiography (ECG)
- Non-invasive beat-to-beat blood pressure from optional external device

The HRV Acquire does not make a diagnosis or indicate by itself any disease state exists. The HRV Acquire is not designed for vital signs monitoring or self monitoring of patients.

3.0 Technological Characteristics
The HRV Acquire device consolidates several components used in the autonomic lab for heart rate variability testing. The primary functions of the HRV Acquire are summarized as:
1. ECG capture of patient heart rate data,
2. Analog data acquisition,
3. Chest Expansion and Expiratory Pressure Capture,
4. Patient cueing metronome for breathing rate,
5. Expiratory pressure target and feedback.

The HRV Acquire device provides ECG signal acquisition (3-lead), inputs for a chest expansion bellows and a valsalva expiratory pressure, and an analog input for an external continuous blood pressure device (optional). In addition, the HRV Acquire device has a large LED display consisting of six 5x7 dot matrix display elements used for patient cueing of a metronome pattern or feedback of valsalva pressure.

The HRV Acquire device includes firmware to provide R-wave detection trigger pulses for heart rate autonomic nervous system diagnostic procedures. The HRV Acquire device is replacing the IVY 101 Patient Monitor which was used for the same purpose of heart rate detection.

The HRV Acquire device will be used in medical research labs and clinics along with the TestWorks software package to support autonomic testing. There are no controls on the device, other than a power ON/OFF switch.
### 3.1 Comparison to Predicates

<table>
<thead>
<tr>
<th>Feature</th>
<th>HRV AQUIRE Device with modified TestWorks Software Under Review</th>
<th>Predicate ANX 3.0 (K941252)</th>
<th>Predicate SphygmoCor Cardiac Vascular Management System (K070795)</th>
<th>Predicate IVY ECG Monitor (K882118, K023616)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use, Indications for Use</td>
<td>The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers: - Expiratory pressure recording and display - Respiratory effort - Breathing cue metronome - Heart rate via electrocardiography (ECG) - Non-invasive beat-to-beat blood pressure from optional device The HRV Acquire is not designed for vital signs monitoring or self monitoring of patients.</td>
<td>Ansar's ANX 3.0 is an Autonomic Nervous System monitoring technology which measures both branches of the Autonomic Nervous System (the sympathetic and the parasympathetic) independently and simultaneously in real-time.</td>
<td>The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises.</td>
<td>The IVY ECG and Heart Rate monitor is a precision ECG patient monitor intended to provide a precisely timed trigger pulse, synchronized with a patient's R-wave. It displays a single ECG waveform, large heart rate, alphanumeric characters for other data, alarm messages, menus and user information.</td>
<td>The HRV Device is applied to perform evaluations of the autonomic nervous system, like the predicate ANSAR and CvMS Devices. The user interface to the HRV Device is through the Test Works software, which is also the user interface to the WR Medical Q-Sweat device, reference 51900 K K992874. The HRV Device contains ECG and Heart Rate functions to replace use of the IVY ECG device during autonomic nervous system evaluations.</td>
</tr>
</tbody>
</table>

| Environment of Use | Hospital, Clinic, Physician Office | Hospital, Clinic, Physician Office | Hospital, Clinic, Physician Office | Hospital, Clinic, Physician Office | Same |
| Duration of use | Diagnostic testing expected to be less than one hour duration. | Diagnostic testing expected to be less than one hour duration. | Diagnostic testing expected to be less than one hour duration. | Diagnostic testing expected to be less than one hour duration. | Same |

| PC Based User Interface Software | Yes WR Medical TestWorks Software | Yes | Yes Test Works Software | Equivalent |

<p>| Energy Type | AC Powered 120 VAC Nominal | AC Powered 120 VAC Nominal | AC Powered 120 VAC Nominal | AC Powered 85 to 264 VAC | Same |
| Size | 10.25 x 6.57 x 1.26 (inches) | Unknown | 12 x 10.3 x 5.3 (inches) | 6.70 x 9.25 x 9.21 (inches) | Equivalent |
| Weight | 2 pounds | Unknown | 5.5 pounds | 6.5 pounds | Equivalent |</p>
<table>
<thead>
<tr>
<th>Feature</th>
<th>IRV AQUIRE Device with modified TestWorks Software Under Review</th>
<th>Predicate SphygmCor™ Cardiac Vascular Management System (K070795)</th>
<th>Predicate IVY ECG Monitor (K882118, K023616)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ECG Specs</strong></td>
<td>CMRR: 90 dB</td>
<td>Unknown specification</td>
<td>CMRR: 90 dB</td>
<td>Equivalent, The HRV Device ECG specifications are defined to support a diagnostic test.</td>
</tr>
<tr>
<td>Lead Selection:</td>
<td>Lead II</td>
<td>Frequency Response: 0.5 to 30 Hz</td>
<td>Lead Selection: LI, LII, LIII</td>
<td></td>
</tr>
<tr>
<td>Ground Isolation:</td>
<td>4 kV rms, 5.5 kV peak</td>
<td>Ground Isolation: 4 kV rms, 5.5 kV peak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Input Impedance:</td>
<td>20 MΩhm at 10 Hz</td>
<td>Input Impedance: 20 MΩhm at 10 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency Response:</td>
<td>0.2 to 100 Hz</td>
<td>Frequency Response: 0.5 to 25 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>R Wave Detection</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Range:</td>
<td>15 to 300 bpm</td>
<td>Unknown specification</td>
<td>Range: 15 to 300 bpm</td>
<td></td>
</tr>
<tr>
<td>Accuracy:</td>
<td>±2%</td>
<td>Accuracy: ±1%</td>
<td>Accuracy: ±1%</td>
<td></td>
</tr>
<tr>
<td>Resolution:</td>
<td>1 bpm</td>
<td>Resolution: 1 bpm</td>
<td>Resolution: 1 bpm</td>
<td></td>
</tr>
<tr>
<td>Sensitivity:</td>
<td>300 µV peak</td>
<td>Sensitivity: 300 µV peak</td>
<td>Sensitivity: 300 µV peak</td>
<td></td>
</tr>
<tr>
<td>Tall T Wave Rejection:</td>
<td>Rejects T waves &lt; R wave</td>
<td>Tall T Wave Rejection: Rejects T waves &lt; R wave</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiration Rate</strong></td>
<td>Yes</td>
<td>Unknown</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Metronome</td>
<td>2-20 seconds</td>
<td>Unknown</td>
<td>No</td>
<td>A display of respiration rate metronome is provided to pace the respiration rate of the patient under test.</td>
</tr>
<tr>
<td><strong>Valsalva</strong></td>
<td>Yes</td>
<td>Unknown range</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Target and Trigger</td>
<td>2 to 50 mmHg</td>
<td>Breath against 40 mmHg</td>
<td>No</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Pressure Setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Alarms</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Same The HRV Device is a diagnostic test device, not a monitoring device.</td>
</tr>
<tr>
<td><strong>Safety Standards</strong></td>
<td>EN/IEC 60601-1 EN/IEC 60601-1-2 AAMI/ANSI EC13</td>
<td>EN/IEC 60601-1 EN/IEC 60601-1-2</td>
<td>EN/IEC 60601-1 EN/IEC 60601-1-2</td>
<td>Additional applicable FDA Recognized Consensus Standards are applied to evaluate the R-R heart rate detection. Compliance is documented in Section 9.0.</td>
</tr>
</tbody>
</table>
4.0 **Data Summary**

Testing of the Heart Rate Variability device was performed in compliance with the WR Medical Electronics CO. design control process. Testing included:

1. Software verification and validation,
2. System verification,
3. Confirmation of compliance with applicable requirements defined in AAMI EC13:2002/(R)2007 Cardiac monitors, Heart Rate Meters and Alarms, and
4. Safety standard compliance.

5.0 **Conclusions**

The safety and effectiveness of the Heart Rate Variability device was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Heart Rate Variability device is the same as the predicate devices. No new questions of safety or effectiveness are raised.
WR Medical Electronics Corporation  
c/o Mr. Gary Syring  
Principal Consultant  
Quality & Regulatory Associates, LLC  
800 Levanger Lane  
Stoughton, WI 53589

Re: K092809  
Trade/Device Name: HRV Acquire  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)  
Regulatory Class: Class II (two)  
Product Code: DRT  
Dated: October 12, 2010  
Received: October 13, 2010

Dear Mr. Syring:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRHOFFices/ucml15809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/ReportaProblern/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 Small Manufacturers, International and Consumer Assistance 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,

[Signature]

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

Enclosure
Indications for Use

510(k) Number (if known): K092809

Device Name: Heart Rate Variability Device

Indications for Use:

The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers:
- Expiratory pressure recording and display
- Respiratory effort
- Breathing cue metronome
- Heart rate via electrocardiography (ECG)
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The HRV Acquire does not make a diagnosis or indicate by itself any disease state exists. The HRV Acquire is not designed for vital signs monitoring or self monitoring of patients.

Prescription Use ___ X ___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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 K092809