January 29, 2020

Athena GTX
Sean Mahoney
VP of Operations and Regulatory Affairs
5900 NW 86th Street, Suite 300
Johnston, Iowa 50131

Re: K191989
Trade/Device Name: Wireless Vital Signs Monitor (WVSM) RWC + miniCap
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, CCK
Dated: December 23, 2019
Received: December 27, 2019

Dear Sean Mahoney:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K191989

Device Name

Wireless Vital Signs Monitor (WVSM) RWC + miniCap

Indications for Use *(Describe)*

The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2, with an optional accessory for capnography (ETCO2, FiCO2, RR). It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer.

The monitor is intended to be used by trained healthcare providers.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER 807.92(a)(1)]:

Athena GTX
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Date Prepared: January 29, 2020

II. DEVICE [807.92(a)(2)]:

Trade Name: Wireless Vital Signs Monitor (WVSM) RWC + miniCap
Common Name: Physiological Patient Monitor
Classification Name: Cardiac Monitor (21 CFR 870.2300)
NIBP Measurement System (21 CFR 870.1130)
Oximeter (21 CFR 870.2700)
Radiofrequency Physiological Signal Transmitter and Receiver (21 CFR 870.2910)
Carbon-Dioxide Gas Analyzer (21 CFR 868.1400)

Device Class: Class II
Product Code: MWI, DXN, DQA, DRG, CCK
Basis for Submission: Device Modification

III. PREDICATE DEVICE [807.92(a)(3)]:

Legally Marketed
(Predicate) Device: Athena GTX, Wireless Vital Signs Monitor (WVSM) (K101674)

IV. DEVICE DESCRIPTION [807.92(a)(4)]:

Device Identification
The WVSM Patient Monitor is a device that monitors physiological parameters associated with Electrocardiogram, Non-invasive Blood Pressure, pulse oximetry and carbon dioxide gas.

Device Characteristics
The WVSM Patient Monitor is a multi-patient use non-sterile device. It utilizes embedded firmware. Patient applied parts are needed for physiological measurement and are provided via FDA cleared OEM accessories to the WVSM monitor.

Environment of Use
WVSM is intended to be used in hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications.

Principle of Operation
The modification to the WVSM includes:

- Adding an indication for capnography by interfacing with a FDA cleared accessory.
- Adding the capability to use the device while connected to the AC power adapter instead of only using the device on battery power.

Materials
The WVSM Patient Monitor enclosure is primarily plastic and does not contact the patient. The applied parts are OEM accessories that are FDA cleared and meet the biocompatibility requirements for intact skin contact. The Aux Battery enclosure is constructed of the same material as the WVSM and does not contact the patient.

Key Performance Specification
Key performance specifications are listed in the table in section VI below.

V. INDICATIONS FOR USE [807.92(a)(5)]:

The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2, with an optional accessory for capnography (ETCO2, FiCO2, RR). It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer.

The monitor is intended to be used by trained healthcare providers.

The Indications for Use statement for the device modification is not identical to the predicate previously cleared device; however, the differences do not alter the general intended use of the WVSM as a multi-parameter monitor nor affect the safety and effectiveness of the device relative to the predicate. The device modification to add an AC power mode does not affect the Indications for use. The modification to add an FDA cleared CO2 gas analyzer as an optional accessory added a capnography indication to the WVSM indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This device modification includes the following:

- Adding capnography by interfacing with a FDA cleared accessory.
- Adding the capability to use the device while connected to the AC power adapter instead of only using the device on battery power.

The WVSM was originally designed to be a multi-parameter monitor and had the AUX port capability built in for future use. Since the capnography accessories are FDA cleared and specifically designed to be connected to a medical backboard (Medical Monitor), this device modification is largely an interface task to connect two cleared devices using a well-established

interface protocol. Therefore the addition of the capnography accessory does not alter the fundamental scientific technology of the WVSM device.
An AC power adapter was already used for charging the internal battery of the previously cleared device. The interface and specifications are the same as the previously cleared device. This modification allows for the modified device to be used while the AC power adapter remains plugged into the monitor. An equivalent and updated AC adapter is used for the modified device. The previously cleared device was used only while on battery power. The addition of this AC power mode does not alter the fundamental scientific technology of the WVSM device.

At a high level, the subject and predicate devices are based on the following same technological elements:

- The Athena GTX WVSM™ device modification and the previously cleared device have the same physical characteristics, cleaning, and cannot be used near flammable anesthetics.
- The Athena GTX WVSM™ device modification and the previously cleared device have the same electrical characteristics including: protection circuits, battery power, and use of AC power adapters.
- The Athena GTX WVSM™ device modification and the previously cleared device have the same environmental specifications for: Temperature, humidity, altitude, water intrusion, vibration, shock, drop, and EMC.
- The Athena GTX WVSM™ device modification and the previously cleared device use the same ECG monitoring circuitry.
- The Athena GTX WVSM™ device modification and the previously cleared device integrate the same PureSAT® pulse oximetry technology to compute functional arterial hemoglobin saturation and pulse rate.
- The Athena GTX WVSM™ device modification and the previously cleared device utilize the same SunTech Advantage OEM Non-invasive Blood Pressure (NIBP) module for mean arterial pressure, and systolic and diastolic blood pressure measurements.
- The Athena GTX WVSM™ device modification and the previously cleared device integrate alarms functions in the monitors.
- The Athena GTX WVSM™ device modification and the previously cleared device utilize 802.11 wireless communications to connect with multiple patient vital signs monitoring devices for bi-directional data transfer.
- The Athena GTX WVSM™ device modification and the previously cleared device utilize software, installed on a PC, to allow for data management and display, alert/alarm management, and patient data review.
- The Athena GTX WVSM™ device modification and the previously cleared device utilize mobile platforms.

The following technological differences exist between the subject and predicate devices:

- The Athena GTX WVSM™ device modification adds an optional capnography accessory not supported in the previously cleared device.
- A different, but equivalent and improved AC power adapter is used with the modified device.
- The AUX Port was modified to be capable of input and output (Same as the DATA port) to support the connection to the capnography accessory.
- Physiological and technical alarms for the capnography parameters (etCO2, FiCO2, RR) and sensor fault respectively were added.

The following is provided as a summary of how the technological characteristics of the device compare to the predicate device:

Product Name	***Athena GTX WVSM RWC + miniCap***	***Athena GTX WVSM Cleared Device***	**Comments**
Manufacturer	Athena GTX	Athena GTX	Same
Trade/Device Name	WVSM RWC + miniCap	WVSM	Different – Device Modification
510(k) Number	Pending – Modified Device	K101674	
Product Code	MWI, DXN, DQA, DRG, CCK	MWI, DXN, DQA, DRG	Different Added CCK
Regulation Number	870.2300, 870.1130; 870.2700; 870.2910, 868.1400	870.2300, 870.1130; 870.2700; 870.2910	Different Added 868.1400
Prescription Device	YES	YES	Same
Physiological Parameters	ECG, heart rate, systolic and diastolic blood pressure; functional oxygen saturation, pulse rate, etCO2, FiCO2, respiration rate	ECG, heart rate, systolic and diastolic blood pressure; functional oxygen saturation, pulse rate	Different – Added etCO2, FiCO2, respiration rate
Displays	Displays ECG, systolic, diastolic BP, SpO2, pulse rate, etCO2, FiCO2, respiration rate	Displays ECG, systolic, diastolic BP, SpO2, pulse rate	Different – Added etCO2, FiCO2, respiration rate
Patient Population	Adult	Adult	Same

Product Name	***Athena GTX WVSM RWC + miniCap***	***Athena GTX WVSM Cleared Device***	Comments
Indications	The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2, with an optional accessory for capnography (ETCO2, FiCO2, RR). It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer. The monitor is intended to be used by trained healthcare providers.	The Wireless Vital Signs Monitor (WVSM) is intended to be used as an adult patient monitor. It is indicated as a single or multi-parameter vital signs monitor for ECG, noninvasive blood pressure (NIBP) and SpO2. It may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications. The monitor uses wireless communications to transmit vital signs data to a handheld or PC computer The monitor is intended to be used by trained healthcare providers.	Different – Added , with an optional accessory for capnography (ETCO2, FiCO2, RR)
Scenario of Use	Continuous or spot monitoring by licensed healthcare professionals	Continuous or spot monitoring by licensed healthcare professionals	Same
Networking/ Telemetry	WVSM may be used standalone or via wireless network (802.11b/g, 2.4GHz) to a handheld or PC computer	WVSM may be used standalone or via wireless network (802.11b/g, 2.4GHz) to a handheld or PC computer	Same
Environment of Use	Emergency medical services, Transport (including helicopter), emergency departments, hospital, other healthcare applications	Emergency medical services, Transport (including helicopter), emergency departments, hospital, other healthcare applications	Same
Physical	No Change		No Changes
Electrical			
Power Modes	Operation: Battery or AC Medical Grade Power Adapter Charging: AC Medical Grade Power Adapter	Operation: Battery Only Charging: AC Medical Grade Power Adapter	Different – Added Operational AC Power mode
Battery	7.4V, 2800 mAh, Li-Polymer	7.4V, 2800 mAh, Li-Polymer	Same
Power Adapter	Mean Well GSM36B09	SL Power/Ault MW173KB Series	Different – Equivalent, meets latest EMC requirements
Environmental	No Changes		No Changes

Product Name	*Athena GTX WVSM RWC + miniCap*	*Athena GTX WVSM Cleared Device*	Comments
Physiological Parameters			
ECG	Internal Circuit	Internal Circuit	Same
Pulse-Ox	Nonin OEM Module	Nonin OEM Module	Same
NIBP	Suntech Medical OEM Module	Suntech Medical OEM Module	Same
Capnography	Masimo OEM Gas Analyzers IRMA (K123043) and ISA (K103604)	NA	Different – Added Capnography
Alarms			
Operator Position *Primary* *Secondary*	Patient Environment Outside Patient Environment (Distributed)	Patient Environment Outside Patient Environment (Distributed)	Same
Verify Alarm Function	1 Second beep at start-up (after menu section). To verify activation at limits, user must simulate alarm condition.	1 Second beep at start-up (after menu section). To verify activation at limits, user must simulate alarm condition.	Same
Silence/Reset	2 min or 30 min Does not affect same or higher priority audible alarm functions	2 min. Does not affect same or higher priority audible alarm functions	Different – Includes an additional silence time
Audible Alarms	No Change		No Change
Alarm Conditions and Priority			
Physiological	High and Low Priority based on Alarm Limits set for each parameter: %SpO2, HR/PR, Systolic BP, Diastolic BP, etCO2, FiCO2, RR	High and Low Priority based on Alarm Limits set for each parameter: %SpO2, HR/PR, Systolic BP, Diastolic BP	Different – Added etCO2, FiCO2, RR
Technical	Low Priority when a sensor fault is detected: SpO2 and Capnography Medium Priority below 5% Battery Power remaining	Low Priority when a sensor fault is detected: SpO2 Medium Priority below 5% Battery Power remaining	Different – Added Capnography sensor fault
Alarm System Delay at the Monitor			
HR/PR	No Change		No Change
SpO2	No Change		No Change
NIBP	No Change		No Change

Product Name	*Athena GTX WVSM RWC + miniCap*	*Athena GTX WVSM Cleared Device*	Comments
IRMA Capnography	Alarm Condition delay <1 sec Alarm Generation Delay 1 sec Total Alarm System Delay <2 sec	NA	Different – Added Capnography
ISA Capnography	Alarm Condition delay <3 sec Alarm Generation Delay 1 sec Total Alarm System Delay <4 sec	NA	Different – Added Capnography
Interfaces			
Data Port	Input/Output, RS232 Used for Wired Connection to PC	Input/Output, RS232 Used for Wired Connection to PC	Same
AUX Port	Input/Output, RS232 Used for connecting Optional Capnography Accessory	Input, RS232 For future use	Different – Added Output capability
Wireless Communication	No Change		No Change
PC and Mobile Application	ADMS	WVSM Management Suite and ADMS	Different – WVSM Management Suite no longer supported

VII. PERFORMANCE DATA [807.92(b)(1)]:

Biocompatibility
The device modification did not change or alter the biocompatibility of the previously cleared device.

Industry Standards for Safety, EMC and Essential Performance
Where applicable, testing of the device modification (WVSM RWC + miniCap) has been completed to verify compliance with recognized national and international standards for safety and performance for medical devices, and particular requirements applicable to this device have not been affected by this modification including:

- IEC 60601-1 Basic safety and essential performance
- IEC 60601-1-2 EMC

Comparison to the Previously Cleared Predicate
Where applicable, side-by-side comparison testing of the device modification (WVSM RWC + miniCap) and the previously cleared device (WVSM Battery operated) has been completed to verify that the devices modifications did not adversely affect the previously cleared device.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Animal Study Data
None.

Clinical Study Data [807.92(b)(2)]:
None.

VIII. CONCLUSION [807.92(b)(3)]:

The results for all safety, compliance, and non-clinical performance testing demonstrates that the Athena GTX the WVSM RWC + miniCap Patient Monitor is substantially equivalent to the above listed predicate device.