June 26, 2024

Athena GTX, Inc.
Sean Mahoney
VP of Engineering & Regulatory Affairs
5900 NW 86th Street, Suite 300
Johnson, Iowa 50131

Re: K233354
Trade/Device Name: WVSM Pro (Series) (500-0030-XX)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DRG, DPS, DRT, DXN, DQA, CCK, FLL
Dated: June 24, 2024
Received: June 24, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jennifer W. Shih -S

Jennifer Shih Kozen
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K233354

Device Name
WVSM Pro (Series) (500-0030-XX)

Indications for Use *(Describe)*
The Wireless Vital Signs Monitor Professional (WVSM Pro) series monitors are intended to be used as continuous or spot check monitors and indicated as single or multi-parameter vital signs monitors. There are two monitor configurations WVSM Pro and TVSM (Tactical Vital Signs Monitor):

WVSM Pro is indicated to monitor electrocardiogram (ECG) 5- or 12-lead waveforms and heart rate (HR); temperature; noninvasive blood pressure (NIBP); Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (Pl); and capnography including end-tidal CO2 (ETCO2), fractional inspired CO2 (FiCO2) and respiration rate (RR).

TVSM is indicated to monitor noninvasive blood pressure (NIBP) and Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (Pl).
The monitors use wireless communications to transmit vital signs data to a PC, laptop, or mobile device.
Patient population: neonate/infant, pediatric and adult patients.

The monitors may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications.

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:

Department of Health and Human Services
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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

**510(k) #: K233354**

Prepared on: 2024-06-21

## CONTACT DETAILS [21 CFR 807.92(a)(1)]

| | |
|---|---|
| Applicant Name | Athena GTX, Inc. |
| Applicant Address | 5900 NW 86th Street, Suite 300, Johnston, Iowa 50131, United States |
| Applicant Contact Telephone | 515-288-3360 |
| Applicant Contact: | Mr. Sean Mahoney |
| Applicant Contact Email | smahoney@athenagtx.com |

## DEVICE NAME [21 CFR 807.92(a)(2)]

| | |
|---|---|
| Device Trade Name | WVSM Pro (Series) (500-0030-XX) |
| Common Name | Cardiac monitor (including cardiotachometer and rate alarm) |
| Classification Name | Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) |
| Regulation Number | 870.2300 |
| Product Code: | MWI, DRG, DPS, DRT, DXN, DQA, CCK, FFL |

## LEGALLY MARKETED PREDICATE DEVICES [21 CFR 807.92(a)(3)]

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K202375 | ZOLL Propaq M | MWI |

## DEVICE DESCRIPTION SUMMARY [21 CFR 807.92(a)(4)]

Wireless Vital Signs Monitor Professional (WVSM Pro) and Tactical Vital Sign Monitor (TVSM) are part of the WVSM Pro Series monitors. The WVSM® Pro series monitors are small, rugged, and highly mobile medical devices intended to be used as an adult, pediatric, and neonate patient vital signs monitor for spot-checking or continuous applications. The monitors are small enough to stay with the patient from point of injury through the triage and treatment process. It is designed as a single or multi-parameter vital signs monitor. The WVSM Pro is capable of acquiring the following physiological parameters: electrocardiogram (ECG) 5- or 12-lead waveforms and heart rate (HR); temperature; noninvasive blood pressure (NIBP); Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI); and capnography including end-tidal CO2 (ETCO2), fractional inspired CO2 (FiCO2) and respiration rate (RR). The TVSM is capable of acquiring the following physiological parameters: noninvasive blood pressure (NIBP) and Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI). Both models can be used as a standalone device or can transmit data via wired and wireless communications to a PC, laptop, or mobile device (tablet or smartphone).

WVSM Pro series monitors are intended for use in pre-hospital, emergency room, inpatient care facilities, healthcare facilities, emergency medical applications, during transport, outpatient care,

and other related healthcare scenarios. The WVSM Pro is intended to be used by trained healthcare providers by prescription only.

The basic principles of operation of the WVSM® Pro Series monitors include:

ECG: 5- or 12-lead waveforms generated via skin electrodes with right-leg drive. Note: The device does NOT include the following functions: Automated Waveform Measurements, Arrhythmia Detection, or Alarms for these functions.

Capnography: Infrared (IR) Spectroscopy is used to detect CO2 concentrations in expired air via mainstream or sidestream methods

Pulse oximetry: The plethysmography waveform from Red and IR LEDs are used to calculate functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI)

Temperature: YSI 400 compatible thermistor sensors

Non-invasive blood pressure (NIBP): Oscillometric method

The WVSM® Pro Series patient monitor enclosures are primarily plastic and is not intended to contact the patient. The applied parts are OEM accessories that are FDA cleared and meet the biocompatibility requirements for intact skin contact.

**INTENDED USE/INDICATIONS FOR USE** [21 CFR 807.92(a)(5)]

The Wireless Vital Signs Monitor Professional (WVSM Pro) series monitors are intended to be used as continuous or spot check monitors and indicated as single or multi-parameter vital signs monitors. There are two monitor configurations WVSM Pro and TVSM (Tactical Vital Signs Monitor):

WVSM Pro is indicated to monitor electrocardiogram (ECG) 5- or 12-lead waveforms and heart rate (HR); temperature; noninvasive blood pressure (NIBP); Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI); and capnography including end-tidal CO2 (ETCO2), fractional inspired CO2 (FiCO2) and respiration rate (RR).

TVSM is indicated to monitor noninvasive blood pressure (NIBP) and Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI).

The monitors use wireless communications to transmit vital signs data to a PC, laptop, or mobile device.

Patient population: neonate/infant, pediatric and adult patients.

The monitors may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications.

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

## INDICATIONS FOR USE COMPARISON [21 CFR 807.92(a)(5)]

The Wireless Vital Signs Monitor Professional (WVSM Pro) series monitors are intended to be used as continuous or spot check monitors and indicated as single or multi-parameter vital signs monitors. There are two monitor configurations WVSM Pro and TVSM (Tactical Vital Signs Monitor):

WVSM Pro is indicated to monitor electrocardiogram (ECG) 5- or 12-lead waveforms and heart rate (HR); temperature; noninvasive blood pressure (NIBP); Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI); and capnography including end-tidal CO2 (ETCO2), fractional inspired CO2 (FiCO2) and respiration rate (RR).

TVSM is indicated to monitor noninvasive blood pressure (NIBP) and Pulse Oximetry including functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), pleth variability index (PVI), and perfusion index (PI).

The monitors use wireless communications to transmit vital signs data to a PC, laptop, or mobile device.

Patient population: neonate/infant, pediatric and adult patients.

The monitors may be used in the following locations: Hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare applications.

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

Predicate Indications Comparison

The WVSM Pro comprises a subset of the indications in the predicate device. The following differences exist between the subject device and the predicate: The WVSM Pro does not include:

- A TBI dashboard
- Invasive pressure monitoring
- 12-Lead analysis

These differences do not affect the safety and effectiveness of the device compared to the predicatewhen used as labeled. The TBI dashboard provides a specific display of data already included in both devices (SBP, etCO2 and SpO2). The trending of these parameters is provided in both, the predicate displays them in a specific popup while the WVSM Pro provides trending of all parameters. The same information can be displayed to the caregiver in both devices. Invasive pressure monitoring is not included in the WVSM Pro series monitors. This is an additional feature for blood pressure monitoring. The WVSM Pro relies on NIBP for blood pressure. This is typical for the intended use of the WVSM Pro. The automated interpretation of ECG waveform analysis is an additional feature of the predicate that is not included in the WVSM Pro. 12-Lead waveforms are provided in the WVSM Pro for caregiver interpretation.

All other indications are the same as the predicate.

**TECHNOLOGY COMPARISON** [21 CFR 807.92(a)(6)]

The following is a summary of the technological characteristics of the WVSM Pro and the predicate device:

- Both use electrodes, lead wires, cables and electronics circuits to provide electrocardiogram (ECG) waveforms for ECG monitoring.
- Both use oscillometric techniques to provide non-invasive blood pressure (NIBP) measurements.
- Both use continuous temperature probes and electronic circuits to provide temperature measurements.
- Both use functional oxygen saturation of arterial hemoglobin to provide a measure of SpO2 and use the plethysmograph (pleth) waveform to calculate pulse rate (PR), pleth variability index (PVI), and perfusion index (PI).
- Both use the concentration of the expired and inspired breath to continuously noninvasively measure and monitor end tidal carbon dioxide and breath rate.
- Both can use separate software to remotely display physiological data.
- Both devices are powered by both battery and an AC adapter.
- Both devices can connect wirelessly to a remote display.

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

- WVSM Pro does not include automated ECG analysis interpretation.
- WVSM Pro does not include invasive pressure measurement.
- WVSM Pro does not have a specific TBI Dashboard display/pop-up.
- WVSM does not have the option to measure respiration rate using impedance pneumography.
- WVSM Pro includes a touch screen display while the predicate has physical buttons to navigate menus and settings.
- WVSM Pro is significantly smaller in size and lighter weight than the predicate device.

These differences do not affect the safety and effectiveness of the device compared to the predicate when used as labeled.

**NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS** [21 CFR 807.92(b)]

NON-CLINCAL TESTING
The following performance data were provided in support of substantial equivalence determination:

BIOCOMPATIBILITY TESTING
No biocompatibility testing was required. The sensors and body contacting applied parts have been previously cleared for patient use. The subject WVSM Pro Series monitors are not patient contacting.

SOFTWARE VERIFICATION AND VALIDATION
Software verification and validation testing was 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." Verification of the WVSM Pro Series monitors was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

# 510(k) Summary

**510(k) #: K233354**

SAFETY AND PERFORMANCE TESTING PER RECOGNIZED STANDARDS
The device was evaluated and found to be in compliance with the standards identified below:

- 19-46 ANSI AAMI ES60601-1 Ed. 3.1 2005/(R)2012 A1:2012, C1:2009/ (R)2012 A2:2010/(R)2012 (Consolidated Text)
- 19-36 IEC 60601-1-2:2014+AMD1:2020 Ed. 4.1 2020-09-01
- 5-132 IEC 60601-1-6 Ed. 3.1 2013-10 Ed. 3.2 2020-07
- 5-131 IEC 60601-1-8 Ed. 2.1 2012-11 Ed. 2.2 2020-07
- 19-39 IEC 60601-1-12+AMD1:2021 Ed. 1.0 2014-06 Ed. 1.1 2020-07
- 3-105 IEC 60601-2-25 Ed. 2.0 2011-10/ (R)2016
- 3-126 IEC 60601-2-27 Ed. 3.0 2011-03
- 3-123 IEC 80601-2-30 Ed 2.0 2018-03
- N/A IEC 60601-2-49 2018
- 1-140 ISO 80601-2-55 Second Ed. 2018-02
- 6-421 ISO 80601-2-56 Second Ed. 2017-03
- 1-139 ISO 80601-2-61 Second Ed. 2017-12 (Corrected ver. 2018-02)
- 3-129 AAMI ANSI EC53 2013

CYBERSECURITY AND WIRELESS TESTING
Cybersecurity considerations were made in accordance with FDA Guidance for Industry and Food and Drug Administration Staff- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, dated October 2, 2014 and draft guidance dated April 8, 2022. To support the subject devices do not raise any new questions of safety and effectiveness compared to the predicate a risk-based assessment and testing in accordance with referenced FDA guidance documents were conducted.

USABILITY TESTING
Usability testing was conducted to evaluate the ability of trained healthcare providers use of the WVSM Pro series monitor with limited training. Subsequently, additional evaluations were conducted on the same users to assess their ability to read and understand the WVSM Pro series monitors instructions for use and simulate normal use after this additional training.

CLINICAL TESTING
Clinical testing was not necessary to show substantial equivalence. The device uses OEM modules for parameters that would normally require clinical testing, NIBP and Pulse Oximetry. These modules have had clinical testing performed and have been used in previously cleared devices. New clinical testing was not necessary.

CONCLUSION
Based on the detailed substantial equivalence comparison, performance testing and conformance with applicable standards the WVSM Pro Series Monitors can be found substantially equivalent to the predicate device with respect to indications for use, technology and intended use.