March 14, 2018

Athena GTX
Sean Mahoney
V.P. Regulatory Affairs
5900 NW 86th Street, Suite 300
Johnston, Iowa 50131

Re: K173203
Trade/Device Name: Athena GTX Device Management Suite (ADMS)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, DRG, MHX, MWI, DSI, DXN, DQA, MLD
Dated: November 3, 2017
Received: November 6, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K173203

Device Name

Athena GTX Device Management Suite (ADMS)

Indications for Use *(Describe)*

The intended use of the ADMS software application is to:

Receive, aggregate, process, distribute and display physiologic waves, parameters, alarms and events at locations other than at the patient, for multiple patients.

Display visual alarm conditions as generated by a connected monitor.

Display of patient information can be real-time or historical record review.

Provide review and trend application data, designed to contribute to the screening of patient condition. All information or visual indications provided are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.

Provide connection to other systems not associated with active patient monitoring, such as information systems. The software performs the action to transfer, store, convert from one format to another according to preset specifications, or to display medical device data.

ADMS is intended for use in professional healthcare facilities, emergency medical applications, during transport, and other healthcare environments by trained healthcare professionals. ADMS Software is not intended for home use.

Indicated for use for specific patient populations (adult, pediatric, infant/neonate) depends on the indicated labeling of medical device(s) connected to ADMS providing the data.

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.

Exhibit H – Section 5 – 510(k) Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

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

Athena GTX
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Date Prepared: January 12, 2018

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

Trade Name: Athena GTX Device Management Suite (ADMS)
Common Name: Physiological Monitors Network and Communication System
Classification Name: Cardiac monitor (incl. cardio tachometer and rate alarm) (21 CFR 870.2300)
Radiofrequency physiological signal transmitter and receiver (21 CFR 870.2910)

Device Class: Class II
Product Code: MSX, DRG
Other Product Codes: MHX, MWI, DSI, DXN, DQA, MLD
Basis for Submission: New Device

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

Legally Marketed
(Primary Predicate) Device: M3290B Patient Information Center iX (PIC iX) (K163584)
(Second Predicate) Device: WVSM Management Suite (K130957)

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

Device Identification
The Athena GTX Device Management Suite (ADMS) is a software only device that manages patient data from compatible monitoring devices.

Device Characteristics
The Athena GTX Device Management Suite (ADMS) receives, distributes and displays physiologic waves, parameters and visual alarms at locations other than at the patient, for multiple patients. Data is generate by compatible connected devices and can be real-time or historical review.

Environment of Use
ADMS is intended for use by trained healthcare providers in hospitals, healthcare facilities, emergency medical applications, during transport, and other healthcare environments.

Principle of Operation
The Athena GTX Device Management Suite provides a method of controlling ADMS compatible devices and viewing the device's data on Android devices (smartphones and tablets), iOS devices (smartphones and tablets) and on PCs running Windows OS.

The ADMS software receives data using Wi-Fi (802.11) from any Athena device within range. Whenever a device comes within range of ADMS, it will start receiving data from the device automatically. Commands to devices is transmitted via Wi-Fi (802.11) to the device. Each platform running ADMS can support viewing up to twenty (20) devices at one time.

Materials
The Athena GTX Device Management Suite (ADMS) consists of software only applications that do not come into physical contact with patients.

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

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

The intended use of the ADMS software application is to:

Receive, aggregate, process, distribute and display physiologic waves, parameters, alarms and events at locations other than at the patient, for multiple patients.

Display visual alarm conditions as generated by a connected monitor.

Display of patient information can be real-time or historical record review.

Provide review and trend application data, designed to contribute to the screening of patient condition. All information or visual indications provided are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.

Provide connection to other systems not associated with active patient monitoring, such as information systems. The software performs the action to transfer, store, convert from one format to another according to preset specifications, or to display medical device data.

ADMS is intended for use in professional healthcare facilities, emergency medical applications, during transport, and other healthcare environments by trained healthcare professionals. ADMS Software is not intended for home use.

Indicated for use for specific patient populations (adult, pediatric, infant/neonate) depends on the indicated labeling of medical device(s) connected to ADMS providing the data.

Exhibit H – Section 5 – 510(k) Summary of Safety and Effectiveness

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The new device (ADMS), the primary predicate and second predicate devices have similar technological characteristics: Software running on off-the-self personal computer and/or mobile platforms that establish a wired or wireless network with connected medical monitors. The second predicate more clearly demonstrates the specific use of a Bi-Directional communication technological characteristic (including adjusting monitor configuration, alarm limits, start/stop taking a blood pressure and initiating a "find" command) between the Software device and the connected medical monitor(s).

Summary points from the specification comparison show that the ADMS and the predicates:

- Use off the shelf operating systems.
- Use both wired and wireless network connections.
- Use off the shelf computers and handheld hardware.
- Provide the same function – central station and remote system patient monitoring.
- Include use in fixed professional healthcare facilities as well as in the field, mobile applications and patient transport locations.
- Provide for real-time/active patient monitoring as well as historical patient record review.
- Include bi-directional communication and control of some monitor functions and configuration settings.
- Provide minimum requirements for hardware and operating system compatibility are specified by the manufacturer – typically in the Instructions for Use (IFU).
- List system compatible monitors typically in the device labeling or in the 510(k) summary.
- Are able to receive, transmit, store, print and display patient information including: waveforms, numerical values, show trends and alarms.
- Are able to interface to Electronic Medical Records data bases via the HL7 protocol.
- Are touch screen compatible.
- ADMS and the secondary predicate have only visual alarms.

The following differences between the predicates and the ADMS software are as follows:

- The primary predicate includes additional ECG waveform analysis and/or display capabilities that are not included in the ADMS.
- The primary predicate has the ability to determine alarm conditions and generate alarm signals for Philips approved medical devices that send physiological data and do not have the ability to determine the alarm condition. This capability is not included in ADMS.
- The primary predicate has both audio and visual alarms, ADMS has only visual alarms. The Secondary predicate has only visual alarms and is the same as ADMS.
- The second predicate does not readily interface with EMRs and does not have an HL7 interface.
- The second predicate does not include Protected Health Information (PHI) data. PHI is included and encrypted in ADMS.

Exhibit H – Section 5 – 510(k) Summary of Safety and Effectiveness

These differences do not raise different questions of safety and effectiveness because they are additional features that are not part of the ADMS functionality or have been included in ADMS for HIPPA and security purposes.

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

Product Element	ADMS (New Device)	PIC iX (Primary Predicate)	WVSM Management Suite (Second Predicate)	Comments
Manufacturer	Athena GTX	Philips Medical Systems.	Athena GTX	- - -
510(k) Number	Pending – new device	K163584	K130957	- - -
Rx Only	Yes	Yes	Yes	Same
Physiological Parameters	Indicated by labeling of the Connected Medical Device	Indicated by labeling of the Connected Medical Device	Indicated by WVSM labeling	Same
Patient Population	Indicated by labeling of the Connected Medical Device	Indicated by labeling of the Connected Medical Device	Indicated by WVSM labeling	Same
User Population	Trained healthcare providers	Trained healthcare professionals	Trained healthcare providers	Same
Operating Systems	Windows 7, 8,10 iOS Android	Windows 10 Windows Server 2012 R2	Window XP iOS	Similar (device platform dependent)
Network/ Connectivity Capabilities	Wired (USB, LAN) WiFi (802.11b/g/n) Cell Network	Wired (LAN) WiFi (802.11)	WiFi (802.11b/g)	Same
Location	Fixed and Field Mobile	Fixed Professional healthcare facilities	Fixed and Field Mobile	Same
Real-time data	Yes	Yes	Yes	Same
Historical/ saved record review	Yes	Yes	No	Same except for WVSM Suite

Exhibit H – Section 5 – 510(k) Summary of Safety and Effectiveness

Product Element	ADMS (New Device)	PIC iX (Primary Predicate)	WVSM Management Suite (Second Predicate)	Comments
Bi-directional Communication with connected monitors	Yes (Configuration, Alarm limits, Start/Stop BP, Find)	Yes (Configuration, Alarm limits, Start/Stop BP, Find)	Yes (Configuration, Alarm limits, Start/Stop BP, Find)	Same
Display	Platform dependent. Minimum requirements specified in the IFU	Minimum requirements specified in the IFU	Platform dependent. Minimum requirements specified in the IFU	Same defined by minimum requirement
Touch Screen Compatible	Yes	Yes	Yes	Same
Host Platforms Supported	Off-the-shelf Windows PCs, servers and iOS/Android mobile devices. Hardware Requirements Specified in IFU	Off-the-shelf Windows PCs and servers. Hardware Requirements Specified in IFU	Off-the-shelf Windows PCs and iOS Mobile devices. Hardware Requirements Specified in IFU	Same defined by minimum requirement
Patient Monitors Supported	Up to 20 devices	Up to 4 devices per patient. Up to 32 Patient Sectors	Up to 20 devices	Same or a subset
Compatible Devices/ Monitors	WVSM (K130957) WiCap (K160582) WiTemp (Not a medical device)	Philips approved medical devices. Examples Include: Bedside: IntelliVue MX and MP Series Portable: IntelliVue X2 Mobile: IntelliVue MX40	WVSM (K130957)	Same System Compatible/ Approved Devices
Types of Data Transmitted, Stored and Displayed	Waveforms, numerical values, trends, Alarms	Waveforms, numerical values, trends, ECG waveform analysis & arrhythmia detection, Alarms	Waveforms, numerical values, trends, Alarms	Same or Subset
Alarms	Visual	Audio and Visual	Visual	Same or Subset
Remote Network Access/ Interface	Yes	Yes (via Web and iPad Accessory)	No	Same for PIC iX

Exhibit H – Section 5 – 510(k) Summary of Safety and Effectiveness

Product Element	ADMS (New Device)	PIC iX (Primary Predicate)	WVSM Management Suite (Second Predicate)	Comments
Print Capability	Yes	Yes	Yes	Same
Data Storage	PHI Saved in an encrypted file, data in a proprietary binary file structure	Not Stated. On a Server	Proprietary binary file structure	Same or Equivalent
Interface to EMR	Yes (HL7)	Yes (HL7)	No	Same except for WVSM Suite

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

Biocompatibility
ADMS is a software only device, does not come in contact with the patient and was not tested for biocompatibility.

Industry Standards for Safety, EMC and Essential Performance
Athena GTX Device Management Suite (ADMS) software is a software only device and therefore all testing was completed under software verification and validation. This submission does not rely on FDA recognized performance standards or device-specific guidance for design or testing.

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 Athena GTX Device Management Suite (ADMS) software has the same performance characteristics and is substantially equivalent to the above listed predicate devices.