February 11, 2022

Zyter, Inc.
% Mary Vater
510(k) Consultant
Medical Device Academy, Inc
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K212622
Trade/Device Name: Zyter RPM
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: August 17, 2021
Received: August 18, 2021

Dear Mary Vater:

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,

for

Jennifer Shih
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)*
K212622

Device Name
Zyter RPM

Indications for Use *(Describe)*
The intended use of the Zyter RPM is to provide an interface with physiological patient monitoring systems to forward recorded device information to the patient's healthcare provider.

Zyter RPM does not alter the behavior of the primary medical devices and associated alert annunciations.

Zyter RPM is not intended to be used for diagnostic purposes. Zyter RPM is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the use environment (e.g., healthcare facility or home setting) and the display interface used. Zyter RPM is a software product and cannot come into physical contact with 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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PRAStaff@fda.hhs.gov

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510(k) SUMMARY

I. SUBMITTER

Zyter, Inc.
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Rockville, MD 20852
Tel: +1.301.355.7760
Fax: N/A

Contact Person: Mary Vater, 510(k) Consultant
Date Prepared: January 6, 2022

II. DEVICE

510(K) Number:	K212622
Name of Device:	Zyter RPM
Classification Name:	Cardiac Monitor (including cardiotachometer)
Regulation:	21 CFR §870.2300
Regulatory Class:	Class II
Product Classification Code:	MSX

III. PREDICATE DEVICE

Primary Predicate Manufacturer:	BoxView, LLC
Primary Predicate Trade Name:	BoxView Smart Alarm Interface (SAI), Model SA-01
Primary Predicate 510(k):	K193421
Secondary Predicate Manufacturer:	EARLYSENSE LTD.
Secondary Predicate Trade Name:	EarlySense Central Display Station (CDS)
Secondary Predicate 510(k):	K151006

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Zyter RPM is a Software as a Medical Device (SaMD) intended to provide healthcare professionals with supplemental information about events and alerts originating from medical devices, or other event or alert producing systems within a clinical or home setting. This device can route notifications including all or a subset of the event or alert information along with related contextual information to selected end points such as but not limited to mobile phones, or other computing or communications end points.

Zyter RPM is intended to provide remote central monitoring and display of information as recorded by multiple specifically compatible FDA cleared devices on a central screen and to provider alert and alert notifications on the screen and to other provider devices.

The Zyter RPM software application will receive, aggregate, process, distribute and display parameters, alerts, and events at locations other than at the patient for multiple patients.

Information provided by the Zyter RPM software is not intended for diagnosis or active patient monitoring where immediate action is required.

Receipt of notifications by the end point is not confirmed, and delivery to the end point is not guaranteed. The primary alert notification is the device or system producing the alert or event.

Zyter RPM is not intended to directly diagnose or treat patients or to be used in the prevention of a disease or condition, nor does Zyter RPM come into direct contact with patients.

Zyter RPM serves as a convenient user interface to integrate data and provide health care professionals the ability to access and monitor parameters of devices and data that have been cleared by the FDA. Zyter RPM does not affect the intended use, or alter the indications for use, for the cleared devices with which it is intended to function.

The Zyter RPM has two separate user interfaces: one is the provider web application and the second is the patient mobile application. The patient mobile application is used by patient-users along with their assigned medical devices to see their own health data and send device readings to their provider. The web application is used by healthcare providers to manage their patients, receive alerts and view their patient's medical data.

Zyter RPM:

Zyter RPM is comprised of two main components:
- Mobile App (for patient users)
- Web App (for healthcare provider users)

The patient mobile application is used by patient-users along with their assigned medical devices to see their own health data and send device readings to their provider. The web application is used by healthcare providers to manage their patients, receive alerts and view their patient's medical data.

The patient-user is provided with a pre-configured Zyter Tablet for remote health monitoring. The patient-user may also choose to use their own smartphone and download the Zyter Mobile App. The patient is also assigned a number of health devices by their healthcare provider. The patient-user is responsible for connecting the health devices to the Zyter Tablet (or mobile phone). Pairing of the health devices with the tablet (or mobile phone) ensures wireless communication between both devices. Instructions for connecting health devices to the patient mobile app are included in the patient app guide. Zyter RPM mobile application also has a functionality that allows the patient to schedule a tele-visit with their healthcare provider. The patient may choose to take a self-assessment questionnaire found in the Zyter RPM prior to scheduling a visit.

Zyter RPM is a digital healthcare platform that automatically collects and routes data from the patient's pre-configured, compatible, at-home medical devices (blood pressure cuffs, glucometers, pulse oximeters, thermometers, digital weight scales, and smart watches) to the hospital physician office via a 4G cellular or Wireless connection.

The health devices are configured to a user in the Zyter user management using the Device Mac address. Zyter validation algorithm doesn't allow the duplicate Mac address entries. Zyter RPM provides patients with Tablets pre-installed with Zyter mobile application. Users connect with the wireless health devices through the mobile app. Zyter also supports BYOD model where patients use their own mobile devices to install the Zyter app from the Apple App store and Google Play store to connect with the wireless devices.

Zyter RPM supports two transmission protocols, device data transmission through Bluetooth technology where the Bluetooth device needs to be paired with the mobile app and the 4G/LTE devices where the device data is transmitted to Zyter via device cloud via APIs and no device pairing required.

Zyter RPM achieves EMR connectivity using on-prem or on-cloud solutions.

The vitals reading from the health devices are securely processed through device SDKs/APIs and they are accessed through the patient and provider RPM dashboard. The Zyter RPM Dashboard enables the monitoring of multiple patients with an information tab for each patient. All physiological patient data, plus alerts and notifications from each patient's RPM devices, go directly to the dashboard for physician review, as well as intervention via a telehealth virtual visit if a patient's readings are out of the normal range.

Physicians can also configure alerts for custom parameters of device readings for individual patients. Zyter RPM devices also send alerts to the physician dashboard, email and SMS, and a reminder to the patient's Zyter RPM app, if a device has been dormant for a pre-determined amount of time.

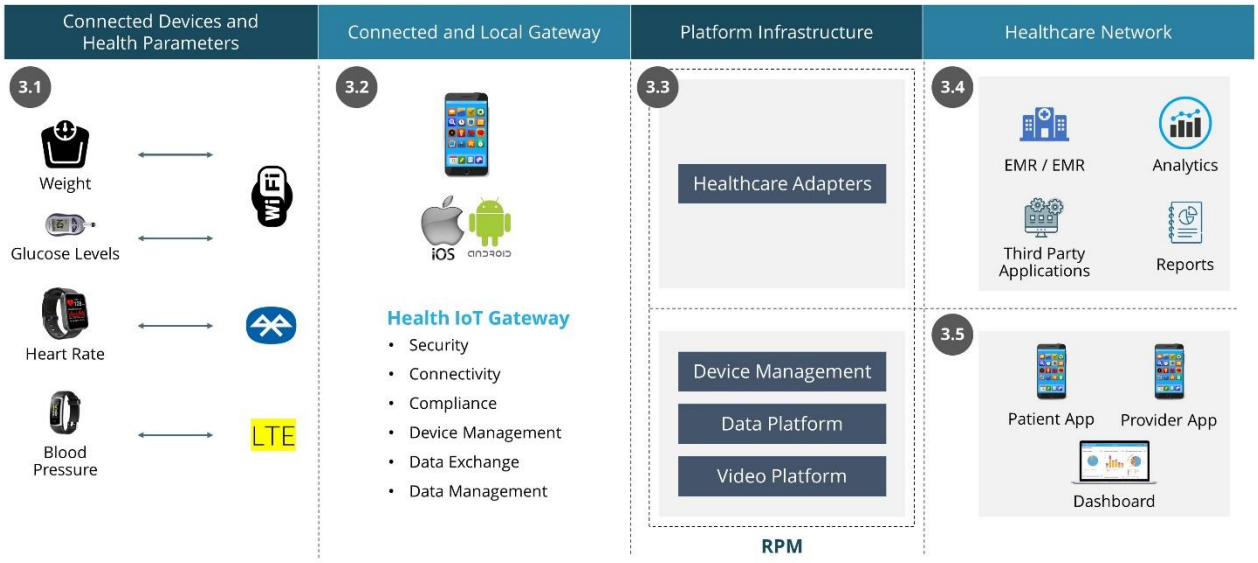
Physicians can set a Zyter RPM alert based on any patient device reading that is out of range. Depending on the device(s) the patient receives, alert ranges can be set to measure the following values:

- BP (Systolic), mmHg
- BP (Diastolic), mmHg
- Pulse Oximeter, % Sp02
- Temperature, F° or C°
- Weight Scale, lbs
- Blood Glucose, mmoI/L

Zyter RPM is compatible with the following medical devices and accessories:

Accessory	510(k) Number
BodyTrace Blood Pressure Monitor	K131395
iHealth BP Monitor - iHealth Track (KN550BT	K160014
BodyTrace Weighing Scale	N/A - Wellness device
iHealth Weighing Scale	N/A - Wellness device
Smart Meter iGlucose Blood Glucose Monitor Starter Kit	K161790
iHealth Blood Glucose - iHealth Gluco + (BG5s):	K181070
iHealth Thermometer PT3	K202753
iHealth Air Pulse Oximeter - iHealth Air (PO3M):	K131111
Nonin Pulse Oximeter	K131021
Apple Health Kit	N/A - Apple Health System

Zyter Component Architecture:



V. INDICATIONS FOR USE

The intended use of the Zyter RPM is to provide an interface with physiological patient monitoring systems to forward recorded device information to the patient's healthcare provider.

Zyter RPM does not alter the behavior of the primary medical devices and associated alert annunciations.

Zyter RPM is not intended to be used for diagnostic purposes. Zyter RPM is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the use environment (e.g., healthcare facility or home setting) and the display interface used. Zyter RPM is a software product and cannot come into physical contact with patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate devices in order to demonstrate substantial equivalence:

	Zyter RPM	**BoxView Smart Alarm Interface (SAI) – K193421**	**EarlySense Central Display Station (CDS) – K151006**
Regulation Number	21 CFR 870.2300	21 CFR 870.2300	21 CFR 870.2300
Regulation Name	Cardiac Monitor (Including Cardiotachometer and Rate Alarm)	Cardiac Monitor (Including Cardiotachometer and Rate Alarm)	Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Primary Product Code	MSX	MSX	MSX
Indications for Use	The intended use of the Zyter RPM is to provide an interface with physiological patient monitoring systems to forward recorded device information to the patient's healthcare provider. Zyter RPM does not alter the behavior of the primary medical devices and associated alert annunciations. Zyter RPM is not intended to be used for diagnostic purposes. Zyter RPM is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the use environment (e.g., healthcare facility or home setting) and the display interface used. Zyter RPM is a software product and cannot come into physical contact with patients.	The intended use of the BoxView Smart Alarm Interface (SAI), Model SA-01 is to provide an interface with physiological patient monitoring systems to forward information associated to an alarm event to a designated display device(s). For medical, near real time alarms, the BoxView Smart Alarm Interface, Model SA-01 is intended to serve as a parallel, redundant, mechanism to inform healthcare professionals of particular medical alarm events. The BoxView Smart Alarm Interface, Model SA-01 does not alter the behavior of the primary medical devices and associated alarm annunciations. The BoxView Smart Alarm Interface, Model SA-01 is intended for use as a secondary alarm notification system. It does not replace the primary alarm function on the monitor.	The Early Sense Central Display System is intended to provide remote central monitoring and display of information as recorded by multiple EarlySense bedside units, on a central remote screen. The system can be used in hospitals or hospital type and clinic environment.

		The BoxView Smart Alarm Interface, Model SA-01 is not intended to be used for diagnostic purposes. The BoxView Smart Alarm Interface, Model SA-01 is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the healthcare facility and the display devices used. The BoxView Smart Alarm Interface, Model SA-01 is a software product and cannot come into physical contact with patients.	
Rx or OTC	Rx only	Rx only	Rx only
Intended User	Healthcare professionals and lay-users	Healthcare professionals	Healthcare professionals

Devices it communicates with	The Zyter RPM supported devices include:
	• Blood pressure Monitoring
	  ○ BodyTrace Blood Pressure Monitor
	  ○ iHealth BP Monitor
	• Weighing scale
	  ○ BodyTrace Weighing Scale
	  ○ iHealth Weighing Scale
	• Glucometer
	  ○ Smart Meter iGlucose Blood Glucose Monitor Starter Kit
	  ○ iHealth Blood Glucose
	• Thermometer
	  ○ iHealth Thermometer PT3
	• Pulse oximeter
	  ○ iHealth Air Pulse Oximeter
	  ○ Nonin Pulse Oximeter
	• Health kit & wearables
	  ○ Apple Health Kit
	• Tablet
		The BoxView SAI provides an interface with physiological patient monitoring systems. Specific medical devices or parameters the primary predicate supports are not referenced in their publicly available 510(k) summary.	The secondary predicate communicates with EarlySense Bedside monitoring devices (K131379 and K120465). The transmitted information from Bedside Unit to CDS and backwards includes alert information and physiological parameters (such as patient in / out of bed status, heart rate, respiration rate, motion rate and SpO2, if monitored at bedside unit, as well as room and bed number, etc.).

	○ Samsung Android Tablet		
Alert/Alarm Interface	Transports alert signals to display devices provided by compatible third-party mobile device companies	Transports alarm signals to display devices provided by compatible third-party mobile device companies	Transports alarm signals from EarlySense Bedside monitoring devices to a central remote screen (EarlySense CDS).
Configurations	Web browser-based application configured to send alert notifications to specific Users. Parameters can be adjusted, e.g., change settable parameters like alert thresholds depending on patient.	Web browser-based application configured to send alarm notifications to specific users	Software application is installed on standard off-the-shelf PC computer with computer screen. Bedside unit's parameters can be adjusted, e.g., change settable parameters like alert thresholds.
Hardware Requirements	<u>Processor and RAM requirements:</u> Processor - Single-core 1Ghz or higher (Minimum); 4GB RAM. <u>Operating Systems:</u> Ubuntu 16.04 macOS X with macOS 10.9, Windows 10, Windows 8 or 8.1 <u>Browser:</u> Chrome 63, FireFox 57 <u>Network:</u> Broadband wired or wireless (3G or 4G/LTE) High-level hardware components needed include: Standard PC with monitor, keyboard, mouse, screen	Minimum Specs for Server: 64-bit (x64) processor, two core; 8GB Ram; 40GB Hard Drive; Linux OS - CentOS 8 or Later (CentOS is a version of Linux); Google Chrome 54.0 or later browser; Network - 100MB.	High-level hardware components needed include: Standard PC with monitor, keyboard, mouse, screen
Communications Operation	Communication performed through HTTPS/WSS protocol, Wireless communications platform, WiFi, hospital infrastructure and BLE or LTE for devices	Wireless communications platform, WiFi, paging technology, hospital infrastructure.	Communication performed through TCP/IP protocol, wireless communication, wired, external communication devices e.g. pagers

Administration	User ID and Password required to enter the configuration manager	User ID and Password required to enter the configuration manager	Not referenced in publicly available 510(k).
Connection to Network	Cloud based application connected through site to-site internet connection	Message integration to hardware on-site via wired Ethernet connections; or Cloud based application connected through site to-site internet connection	Communication performed through TCP/IP protocol, via standard wired or wireless LAN
Logging	Zyter RPM stores messages (encrypted), alerts, RPM Notes, Device readings.	Stores messages, alarms, faults, input/output activities.	Not referenced in publicly available 510(k).
User Interface	Cloud based application with the user dashboard, where users can view alert messages and reading values, add notes and set parameters, such as alert thresholds.	Accept or reject messages if busy – automatically redirect to another caregiver.	Users can access user interface of individual bedside units via the CDS's screen and view or adjust bedside unit's parameters, e.g. change settable parameters, such as alert thresholds. Remote view of the CDS screen from a tablet or additional PC computer is also possible.
Alarm Configuration	Filter to provide specific alert signals to specific providers	Filter to provide specific alarm signals to specific caregivers	Not referenced in publicly available 510(k).
Performance Testing	Performance testing of the Zyter RPM included: 1. Risk Analysis 2. Software verification and validation 3. Performance bench testing Performance testing done on number of concurrent transaction (readings from device or alerts generated from a reading) APIs can handle within a stipulated interval. The transactions are stimulated through auto scripts to the test the server capacity to identify when the application performance begins to degrade.	The bench performance test for Smart Alarm Interface involves simulating alert/alarm messages from concurrent alert/alarm sources to validate that below and at server capacity the alarm messages filter correctly and that notifications send to caregiver devices when applicable. Another bench performance test will involve simulating alert/alarm messages over server capacity to identify when the application performance begins to degrade.	Performance testing of the EarlySense CDS included: 4. Risk Analysis 5. Software verification and validation 6. Performance bench testing

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Not Applicable (Standalone Software)

Biocompatibility Testing

Not Applicable (Standalone Software)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Passive Device)

Software Verification and Validation Testing

Software verification and validation testing was conducted in compliance with ANSI/AAMI/IEC 62304:2006/A1:2016 Medical device software -Software life cycle processes, and the following FDA Guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Guidance for Industry and Food and Drug Administration Staff, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for Industry and Food and Drug Administration Staff – Postmarket Management of Cybersecurity in Medical Devices

Human Factors Testing

A summative human factors study was conducted to evaluated the usability of the subject device by the intended users. The usability studies were conducted in compliance with ANSI/AAMI/IEC 62366-1:2015/A1:2020, and the following FDA Guidance document:

- Guidance for Industry and Food and Drug Administration Staff Applying Human Factors and Usability Engineering to Medical Devices

Animal Study

Animal performance testing was not required to demonstrate substantial equivalence of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the substantial equivalence of the device.

VIII. CONCLUSIONS

The Zyter RPM is substantially equivalent to the identified predicates in terms of design features, fundamental scientific technology, and intended use. Substantial equivalence has been demonstrated with non-clinical performance testing. The verification and validation results provided in this 510(k) premarket notification demonstrate that the subject device, Zyter RPM, is substantially equivalent to the identified predicate devices.