



September 30, 2025

TigerConnect
% Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K243270

Trade/Device Name: TigerConnect Alarm Management
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, PHC
Dated: March 6, 2025
Received: March 6, 2025

Dear Thomas Kroenke:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

KIMBERLY N. CROWLEY -S Digitally signed
by KIMBERLY N.
CROWLEY -S

For: Jennifer 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

Indications for Use

Submission Number (if known)

K243270

Device Name

TigerConnect Alarm Management

Indications for Use (Describe)

The intended use of TigerConnect Alarm Management is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s).

For medical alarms, TigerConnect Alarm Management is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. TigerConnect Alarm Management does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audible and/or vibrating mechanism upon receipt of the alert.

TigerConnect Alarm Management is intended for use as a secondary alert. It does not replace the alarm function on the primary device.

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.

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510(k) Summary
(in accordance with 21 CFR 807.92)

Submission Date: 28 February 2025

Submitter: TigerConnect
2054 Broadway
Santa Monica, CA 90404 USA

Submitter Contact: Mr. Steve Tyler
Phone: +1 (260) 341-2702
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Official Contact: Mr. Thomas Kroenke
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Manufacturing Site: TigerConnect
2054 Broadway
Santa Monica, CA 90404 USA

Trade Name: TigerConnect Alarm Management

Classification Name: System, Network And Communication, Physiological Monitors

Primary Classification Regulation / Product Code, and Name 21 CFR §870.2300 / MSX
System, Network And Communication, Physiological Monitors

Secondary Classification Regulations / Product Code, and Name 21 CFR §880.5725 / PHC
Infusion Safety Management Software

<i>Substantially Equivalent Devices:</i>	<i>Proposed TigerConnect Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
	TigerConnect Alarm Management	K193043	Critical Alert / Critical Alert CommonPath (Primary Predicate)
		K193421	BoxView, LLC / BoxView Smart Alarm Interface (SAI), Model SA-01

Device Description: TigerConnect (TC) Alarm Management is a software as a medical device (SaMD) installed on the Amazon Web Services (AWS) TigerConnect cloud capable of acquiring alarms, events, and parameters from healthcare systems, and intelligently forwarding this information as secondary notifications to designated commercial endpoint devices. The endpoint devices act as non-regulated medical device data system (MDDS) devices that display the information from TC Alarm Management.

TC Alarm Management is intended for use as a secondary alarm; it does not replace the alarm function on the primary device.

Users receive interactive, time-critical information from clinical systems directly via their endpoint devices as text (visual) or alarms (audible) or data. Received attributes related to the presentation of alerts include color and quantity of tones (beeps) in addition to, and in coordination with, event priorities. TC Alarm Management allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

A portion of the software, the Health Services Agent, is deployed to the customers' premises using ECS Anywhere, an extension of Amazon ECS that allows customers to run native ECS tasks on customer-managed infrastructure without compromising on the simplicity and control of the cloud. ECS Anywhere must be deployed in a customer provided virtual machine prior to implementing the Health Systems Agent. This allows TC Alarm Management to securely send, receive, process, and appropriately encrypt data from systems that are typically unencrypted.

TC Alarm Management connects to the information sources through wired ethernet connections which are part of the customer's infrastructure and acquires patient data from primary medical device sources and clinical systems. TigerConnect implementation engineers configure TC Alarm Management, in collaboration with the customer, to determine which information, including alarm notifications, is delivered to which users. TC Alarm Management then formats the data for wireless delivery to the endpoint devices through TigerConnect's proprietary Clinical Collaboration Platform (CCP) non-regulated MDDS messaging service.

***Device Description
(continued):***

TC Alarm Management is designed to accept inputs from a variety of healthcare systems utilizing the HL7 Minimum Lower Layer Protocol (MLLP) communication protocol. These clinical systems include the following:

- Medical device gateways providing HL7 MLLP communications, which includes, but is not limited to, the following parameters and events surrounding them, e.g. alarms:
 - Patient monitors such as electrocardiograms (ECGs), respiratory rate, pulse oximetry (SpO₂ and heart rate), end-tidal carbon dioxide (EtCO₂), non-invasive blood pressure, cardiac output, temperature and associated derived outputs.
 - Lung ventilators.
 - Respiratory gas monitors.
 - IV infusion (including patient-controlled analgesia) pumps.
- Nurse call systems.
- Electronic health record (EHRs) systems.

TC Alarm Management provides a wireless communications system platform for delivery of secondary notifications to endpoint devices with Android or iOS operating systems (OSs) through the CCP messaging service.

Intended Use:

The intended use of TigerConnect Alarm Management is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s).

For medical alarms, TigerConnect Alarm Management is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. TigerConnect Alarm Management does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audible and/or vibrating mechanism upon receipt of the alert.

TigerConnect Alarm Management is intended for use as a secondary alert. It does not replace the alarm function on the primary device.

Technology Comparison:

The TC Alarm Management employs the same technological characteristics as the predicate device.

<i>Characteristic</i>	<i>Critical Alert CommonPath Enterprise (K193043)</i>	<i>TigerConnect Alarm Management (Subject Device)</i>	<i>Discussion of Differences</i>
<i>Intended Use</i>	<p>The intended use of Critical Alert CommonPath Enterprise is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s). For medical, near real time alarms, Critical Alert CommonPath Enterprise is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. Critical Alert CommonPath Enterprise does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audible and/or vibrating mechanism upon receipt of the alert.</p> <p>Critical Alert CommonPath Enterprise is intended for use as a secondary alert. It does not replace the alarm function on the primary device.</p>	<p>The intended use of TigerConnect Alarm Management is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s). For medical alarms, TigerConnect Alarm Management is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events TigerConnect Alarm Management does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audible and/or vibrating mechanism upon receipt of the alert.</p> <p>TigerConnect Alarm Management is intended for use as a secondary alert. It does not replace the alarm function on the primary device.</p>	Same.
<i>Primary Product Code, Regulation</i>	MSX, 21 CFR §870.1025	MSX, 21 CFR §870.1025	Same.
<i>Secondary Product Code, Regulation</i>	PHC, 21 CFR §880.5725	PHC, 21 CFR §880.5725	Same.
<i>Serves as secondary means of annunciating patient events</i>	Yes	Yes	Same

Technology Comparison (continued):

<i>Characteristic</i>	<i>Critical Alert CommonPath Enterprise (K193043)</i>	<i>TigerConnect Alarm Management (Subject Device)</i>	<i>Discussion of Differences</i>
<i>Location of software</i>	Customer's internal servers	AWS TigerConnect cloud servers The Health Service Agent is downloaded to customer's internal server	The reference predicate BoxView, LLC Smart Alarm Interface (SAI), Model SA-01 (K193421), product code MSX, offers a version of their software that is located on an AWS cloud server.
<i>Required customer computer hardware</i>	<p>Typical rack mount server from a vendor such as Dell or HP.</p> <ul style="list-style-type: none"> • Memory – 16 GB RAM • Hard Disk Storage – 4 x 500 GB 15K RPM - Raid 10 • Processor – 2 x 3.0 GHz Quad Core (4 core minimum) • NIC – Support for 10-100Mbit (minimum) 	<p>Two (2) virtual machines (VMs) for the Health Service Agent (minimum of 1 VM):</p> <ul style="list-style-type: none"> • Memory <ul style="list-style-type: none"> ○ Development/Testing – Minimum 4 GB ○ Production – Minimum 8 GB • Hard Disk Storage <ul style="list-style-type: none"> ○ Development and Production – Minimum 4 GB, thin provisioned • Processor – Minimum 2 x 3.0 GHz Quad Cores • NIC – Minimum 1 Gbit/sec. 	
<i>Duty assignments</i>	<p>Tested for 141 number of locations (units) supported. Redirection level: Typically no more than 6.</p>	<p>Tested for 141 number of locations (units) supported. Redirection level: Typically no more than 3.</p>	<p>Assignments are used during workflow configuration. Once workflows are configured and verified, the source of assignment resources is not utilized by TigerConnect Alarm Management. These differences do not raise new questions of safety or effectiveness.</p>
	<p>Assignments is a web-based application and not a client. Can be accessed from any PC with user authentication. Grid with room number / patient name with point and click caregiver assignment. Supports shift planning and assignment of display and/or alerting devices to staff members. Supports assignment of staff to patients with escalation chains. Assignment summary provides information of unassigned patients or devices. Tested for 14,000 number of assignees. Tested for 14,000 number of locations and events (e.g. 141 locations/units with ~100 assignable events per location).</p>	<p>TigerConnect Alarm Management does not have assignment functionality. It relies on clinical API standards to access assignment resources from either a connected nurse call system (NCS) or electronic health record (EHR) system.</p>	
<i>Time sources</i>	NIST server compatible. Time can be set manually.	NIST server compatible. Time can be set manually.	Same.

Technology Comparison (continued):

<i>Characteristic</i>	<i>Critical Alert CommonPath Enterprise (K193043)</i>	<i>TigerConnect Alarm Management (Subject Device)</i>	<i>Discussion of Differences</i>
<i>Messaging component compatibility list</i>	HL7 (v2.5 or higher) TAP (v1.8)	HL7 (v2.0 or higher).	TigerConnect Alarm Management utilizes a subset of the predicate. These differences do not raise new questions of safety or effectiveness.

Performance Testing:

Software, Cybersecurity, and Interoperability

TC Alarm Management is ENHANCED software. Software was designed and developed according to a robust software development process and was rigorously verified and validated. Software information is provided in accordance the following standards and guidance documents:

- *AAMI TIR57: 2016, Principles for medical device security – Risk management.*
- *ANSI/AAMI SW91: 2018, Classification of Defects in Health Software.*
- *ANSI/AAMI 2700-1: 2019, Medical Devices And Medical Systems – Essential Safety And Performance Requirements For Equipment Comprising The Patient-Centric Integrated Clinical Environment (ICE) – Part 1: General Requirements And Conceptual Model.*
- *IEC 62304: 2015, Medical device software – Software life cycle processes.*
- *ISO 14971: 2019, Medical devices – Application of risk management to medical devices.*
- *FDA guidance: The content of premarket submissions for software contained in medical devices, 14 Jun 23.*
- *FDA guidance: Off-the-shelf software use in medical devices, 11 Aug 23.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *NTIA guidance: Framing Software Component Transparency: Establishing a Common Software Bill of Materials (SBOM), 21 Oct 21.*
- *FDA guidance: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) software, 14 Jan 05.*
- *FDA guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, 27 Sep 23.*
- *FDA guidance: Postmarket Management of Cybersecurity in Medical Devices, 28 Dec 16.*

*Software,
Cybersecurity, and
Interoperability
(continued)*

- *FDA guidance: Postmarket Management of Cybersecurity in Medical Devices, 28 Dec 16.*
- *FDA guidance: Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *FDA guidance: Infusion Pumps Total Product Life Cycle, 02 Dec 14.*

Test results indicate that the TC Alarm Management complies with its predetermined specifications and the applicable standards and guidance documents.

*Performance Testing
– Bench*

TC Alarm Management was tested for performance in accordance with internal requirements, applicable portions of the following standards, and the following guidance document:

- *IEC 60601-1-8: 2021, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Test results indicate that the TC Alarm Management complies with its predetermined specifications, applicable portions of the following standards, and the applicable guidance document.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the TC Alarm Management. The results of these activities demonstrate that the TC Alarm Management is as safe and as effective in comparison to the predicate device when used in accordance with its intended use and labeling.

Therefore, the TC Alarm Management is considered substantially equivalent to the predicate device.