May 11, 2020

Critical Alert
% Thomas Kroenke
Principal Consultant
Speed to Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K193043
Trade/Device Name: Critical Alert CommonPath Enterprise
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, PHC
Dated: March 30, 2020
Received: March 31, 2020

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 (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,

Jennifer Shih
Assistant Director (Acting)
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

510(k) Number (if known): K193043

Device Name: Critical Alert CommonPath Enterprise

Indications For Use: 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.

Critical Alert CommonPath Enterprise is intended for use as a secondary alert. It does not replace the alarm function on the primary device.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

510(k) Summary (K193043)

Submission Date:	11 May 2020
Submitter:	Critical Alert 4901 Belfort Road, Suite 130 Jacksonville, FL 32256
Submitter Correspondent	Mr. John Elms Phone: +1 (904) 260-6334 Email: JElms@criticalalert.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net +1 (303) 956 4232
Manufacturing Site:	Critical Alert 4901 Belfort Road, Suite 130 Jacksonville, FL 32256
Trade Name:	Critical Alert CommonPath Enterprise
Common Name:	Physiological Monitors Network And Communication System
Classification Name:	Physiological Monitors Network And Communication System
Classification Regulation:	21 CFR §870.2300, 21 CFR §880.5725
Product Code:	MSX, PHC

Substantially Equivalent Devices:	*New Critical Alert Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Critical Alert CommonPath Enterprise	K180566	Ascom Sweden AB / Unite Connect for Clinical Systems (Primary)
		K130208	Cardiopulmonary Corporation / Bernoulli Enterprise Software (Secondary)

510(k) Summary (K193043)

Device Description: Critical Alert CommonPath Enterprise (CommonPath) is a software application installed on a Windows server environment capable of acquiring alarms, events, and parameters from clinical systems and intelligently forwarding this information as notifications to designated display devices provided by third-party mobile device companies.

Critical Alert CommonPath Enterprise 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 display devices as text (visual) or alarms (audible) or data. Received attributes related to the presentation of alerts include text and tones (beeps) in addition to and in coordination with event priorities. CommonPath allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

CommonPath connects to the information sources through wired ethernet connections which are part of the customer's infrastructure and acquires patient data from clinical systems. The user configures CommonPath to determine which information, including alarm notifications, is delivered to which users. CommonPath then formats the data for wireless delivery to the display devices through a messaging server.

Indications for Use: 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.

Critical Alert CommonPath Enterprise is intended for use as a secondary alarm. It does not replace the alarm function on the primary device.

Technology Comparison:

Critical Alert CommonPath Enterprise employs the same technological characteristics as the predicate device.

Characteristic	***Ascom Sweden AB Unite Connect for Clinical Systems (K180566)***	***Critical Alert CommonPath Enterprise (Proposed Device)***
Indications for Use	The intended use of the Ascom Unite Connect for Clinical Systems 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, the Connect for Clinical Systems is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. Connect for Clinical Systems does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audio and/or vibrating mechanism upon receipt of the alert. Connect for Clinical Systems is intended for use as a secondary alarm. It does not replace the primary alarm function on the monitor.	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. Critical Alert CommonPath Enterprise is intended for use as a secondary alarm. It does not replace the alarm function on the primary device.
Serves as secondary means of annunciating patient events	Yes	Same
Uses computer hardware to gather and format alarm event information	Windows-based personal computer (PC) • Memory: 4 GB RAM • Processor: 2 GHz • Connection: TCP/IP base LAN Disk Space: 50 GB minimum (recommended free disk space for installation)	Typical rack mount server from a vendor such as Dell or HP. • Memory – 16 GB RAM • Hard Disk – 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)

Technology Comparison (continued):

Characteristic (continued)	***Ascom Sweden AB Unite Connect for Clinical Systems (K180566)***	***Critical Alert CommonPath Enterprise (Proposed Device)***
Duty assignments	Scale is based on maximum number of locations supported per integration. Current maximum number of locations: 128 Maximum number of concurrent assignment clients: 30 Maximum redirection levels: 3 Supports a fully configurable location layout. Supports assignment clients with shift planning and assignment of display and/or alerting devices to staff members. Supports assignment of staff to patients with escalation chains. Unassigned location warning when a location or a group of events are not assigned. Maximum number combined assignees: 6,000 Maximum number of combined locations and events per location: 1,200 (e.g. 128 locations with ~9 assignable events per location)	Tested for 141 number of locations (units) supported. Assignments is a web-based application and not a client. Can be accessed from any PC with user authentication. Typically no more than 6. 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)
Time sources	NTP server (NTPv4 compatible with NTPv2 and NTPv3). Time can be set manually from a Web browser.	NIST server compatible. Time can be set manually.
Messaging component compatibility list	Unite Connectivity Manager (v5.10.0 and higher) Unite Communication Server (1.3.1 and higher) TAP (v1.01) ECG-SNPP (v1.03) ECG-OAI (2.05) ECG-Cisco (1.21) SMTP (2.24)	CommonPath Enterprise (v2.1.6 and higher)

510(k) Summary (K193043)

Summary of Performance Testing:

Software

Critical Alert CommonPath Enterprise software was designed and developed according to a robust software development process and was rigorously verified and validated.

Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14.*
- *Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) software, 14 Jan 05.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *Infusion Pumps Total Product Life Cycle, 02 Dec 14.*

Test results indicate that Critical Alert CommonPath Enterprise complies with its predetermined specifications and the guidance documents.

Performance Testing – Bench

Critical Alert CommonPath Enterprise was tested for performance in accordance with internal requirements and the following standard.

- *IEC 60601-1-8: 2012, 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 (Clause 6.11 only).*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*

Test results indicated that Critical Alert CommonPath Enterprise complies with internal requirements and the applicable Standard.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to Critical Alert CommonPath Enterprise. The results of these activities demonstrate that Critical Alert CommonPath Enterprise is as safe and as effective in comparison to the predicate device when used in accordance with its intended use and labeling.

Therefore, Critical Alert CommonPath Enterprise is considered substantially equivalent to the predicate device.