April 3, 2018

Ascom Sweden AB
% Thomas Kroenke
Principal Consultant
Speed to Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K180566
Trade/Device Name: Unite Connect for Clinical Systems
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: February 28, 2018
Received: March 5, 2018

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. 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,

Nicole G. Ibrahim -S

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)*
K180566

Device Name

Ascom Unite Connect for Clinical Systems

Indications for Use *(Describe)*

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, 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.

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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"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

Submission Date:	28 February 2018
Submitter:	Ascom Sweden AB Grimbodalen 2 Göteborg, SE-402 76 Sweden
Submitter and Application Correspondent	Mr. Ivan Liljegren Phone: +011 46 31 55 93 11 Email: Ivan.Liljegren@ascom.com
Manufacturing Site:	Ascom Sweden AB Grimbodalen 2 Göteborg, SE-402 76 Sweden
Trade Name:	Ascom Unite Connect for Clinical Systems
Common and Classification Name:	System, Network and Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:

New Ascom Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Ascom (US), Inc. / ClinicalConneX | Cardiomax	K103634	Ascom Sweden AB / Unite Connect for Clinical Systems

Device Description:

Ascom Sweden AB (Ascom) Unite Connect for Clinical Systems (Unite Connect) is a software application installed on a Windows server environment capable of acquiring alarms, events, parameters and waveforms from clinical systems and intelligently forwarding that information as notifications to designated display devices provided by Ascom or third-party mobile device companies. The device operates within the Ascom Unite Messaging Suite for Healthcare application environment.

Unite Connect is designed to accept inputs from a variety of clinical systems utilizing standardized and proprietary protocols including the following:

- Spacelabs XprezzNet
- Dräger Infinity Gateway

510(k) Summary

Device Description (continued):

Users receive interactive, time-critical information from clinical systems directly via their display devices as text, alarms, static waveform images 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. Unite Connect allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

Unite Connect 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 Unite Connect to determine which information, including alarm notifications, is delivered to which users. Unite Connect then formats the data for wireless delivery to the display devices through Unite Connectivity Manager (Unite CM) or the Unite Communication Server (Unite CS).

All messaging activities are recorded in Unite CM or Unite CS providing real-time activity logging for audit trail records and reporting. Unite Connect delivers near real-time text messaging alerts and information to text-capable display devices.

Ascom provides wireless communications system platform for delivery of notifications to display devices, the technologies include DECT (Digital Enhanced Cordless Telecommunications), WiFi, Paging and GSM/3G/4G.

Unite Connect, combined with an Ascom wireless communication system, is part of an Ascom end-to-end solution designed to provide all the components necessary to optimize work flow, including display devices, gateways and device management.

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, 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.

510(k) Summary

Technology Comparison:

Unite Connect employs the same technological characteristics as the predicate device.

Characteristic	***Predicate Device***	***Proposed Device***
Indications for Use	The Ascom ClinicalConneX | Cardiomax (Cardiomax) 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 Ascom Cardiomax is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. Ascom Cardiomax 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. The Ascom Cardiomax is intended for use as a secondary alarm. It does not replace the primary alarm function on the monitor.	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.
Serves as secondary means of annunciating patient events	Yes	Same.
Uses computer hardware to gather and format alarm event information	Ascom Sweden AB Elise2 module • Memory: 64 MB RAM, 1GB Flash • Lan connection: 10baseT or 100baseT Ethernet (RJ45) Error relay output: Active when the relay operates or is released serial: 3 RS232 ports (RJ45)	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)

510(k) Summary

Technology Comparison (continued):

Characteristic	***Predicate Device***	***Proposed Device***
Duty assignments	Includes support for up to 100 Assignment Locations and 1 concurrent Duty Assignment Client. Up to 5 escalation levels. Fully configurable location layout. Fully configurable available users per location. Unassigned event warning.	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)
Time sources	NTP server (NTPv4 compatible with NTPv2 and NTPv3). Time can be set manually from a Web browser.	Same.
Messaging component compatibility list	Unite Connectivity Manager (v1.11) IMS2 (v2.72) ACS (v2.17) ECG-Cisco (v1.21), ECG-OAI (v2.05) ECG-SMTP (v2.24) ECG-SNPP (v1.03) ECG-TAP (v1.01)	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)

510(k) Summary

Summary of Performance Testing:

Software

Unite Connect is MODERATE level of concern 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 with internal requirements and the following guidance documents:

- *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.*
- *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *IEC 62304: 2006, Am1: 2015, Medical device software - Software life cycle processes*

Test results indicate that Unite Connect complies with its predetermined specifications and the applicable guidance documents and standards.

Performance Testing – Bench

Unite Connect was verified for performance in accordance with internal requirements and the following standards:

- *IEC 60601-1-8: 2006, Am1: 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*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*

Verification results indicate that Unite Connect complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of Unite Connect. The results of these activities demonstrate that Unite Connect is ubstantially equivalent to the predicate devices.