November 23, 2018

ASCOM UMS srl unipersonale
% Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K180430
Trade/Device Name: Digistat Smart Central
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, PHC
Dated: October 24, 2018
Received: October 25, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Arielle Drummond -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K180430

Device Name: Digistat Smart Central

Indications For Use: The intended use of the Digistat Smart Central is to provide an interface with clinical systems to forward information associated to the particular event from patient monitors, ventilators, and infusion pumps to the designated display device(s). For medical, near real time alarms, the Digistat Smart Central is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. The Digistat Smart Central 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 Digistat Smart Central is intended for use as a secondary alarm. It does not replace the primary alarm function on the medical devices.

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

Submission Date:	07 November 2018
Submission Number:	K180430
Submitter:	ASCOM UMS srl unipersonale Via Amilcare Ponchielli 29 50018 Scandicci (FI), Italy
Submitter Correspondents	Mr. Paolo Burchietti Phone: +011 39 055 051 2161 Email: paolo.burchietti@ascom.com Mr. Ivan Liljegren Phone +011 (46) 31 55 93 11 Email: ivan.liljegren@ascom.com
Application Correspondent	Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 Mr. Thomas Kroenke Phone: +1 (303) 956-4232 Email: tkroenke@speedtomarket.net
Manufacturing Site:	ASCOM UMS srl unipersonale Via Amilcare Ponchielli 29 50018 Scandicci (FI), Italy
Trade Name:	Digistat Smart Central
Primary Classification Name, Regulation, and Product Code:	System, Network and Communication, Physiological Monitors 21 CFR §870.2300 MSX
Secondary Classification Name, Regulation, and Product Code:	Infusion Safety Management Software 21 CFR §880.5725 PHC

510(k) Summary

Substantially Equivalent Devices:	*New Ascom Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Digistat Smart Central	K103634	Ascom (US), Inc. / ClinicalConneX | Cardiomax
		K130208 (Reference)	Cardiopulmonary Corporation / Bernoulli Enterprise Software
		K130707 (Reference)	iSirona, LLC / iSirona Magellan

Device Description: Digistat Smart Central is an on-site integration solution which forwards medical device status and alarm information to the user via display devices provided by Ascom or third-party companies. Users receive, time-critical information from connected medical devices directly via their display devices as text, alarms or data. Digistat Smart Central allows users to be aware of their patients' status and alarm conditions when they are away from the patient and associated medical devices.

Digistat Smart Central connects to the information sources through wired ethernet connections which are part of the customer's infrastructure. Digistat Smart Central software acquires patient data and information through DIGISTAT Connect, a MDDS, from medical devices including patient monitors, ventilators, and infusion pumps. The user configures Digistat Smart Central to determine which information, including alarm notifications, is delivered to which users. Digistat Smart Central then formats the data for delivery to the display devices.

Digistat Smart Central is not in contact with the patient. It is intended to forward the information generated by the connected medical devices and systems and it does not generate patient related alarms. As such, the patient population and patient conditions are established by the medical devices and systems to which the product is connected.

510(k) Summary

Indications for Use: The intended use of the Digistat Smart Central is to provide an interface with clinical systems to forward information associated to the particular event from patient monitors, ventilators, and infusion pumps to the designated display device(s). For medical, near real time alarms, the Digistat Smart Central is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. The Digistat Smart Central 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 Digistat Smart Central is intended for use as a secondary alarm. It does not replace the primary alarm function on the medical devices.

Technology Comparison: The Digistat Smart Central employs the same technological characteristics as the predicate device.

Characteristic	***Predicate Device***	***Proposed Device***
Serves as secondary means of annunciating patient events	Yes	Same.
Relays information from the medical devices to desktops and mobile caregivers	Yes, patient monitors	Yes, patient monitors, ventilators, infusion pumps, hemodialysis machines, and infant incubators.
Caregiver is alerted via audible and/or vibratory tones when mobile display device receives an alarm event transmission	Yes	Same
Alarm event notifications can be stored on display device for later reference	Last 10 - 50 stored depending upon display device.	Complete history of events is stored in the product database. Display devices can show full history of the events for the patient. Default filter shows just the last hour of events.
Type of alarm	Yes	Same.
Vital signs	Yes	Same.
Waveform data	No	Same.

510(k) Summary

Summary of Performance Testing:

Software

The Digistat Smart Central software 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.*
- *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.*
- *IEC 62304: 2006, Medical device software - Software life cycle processes*

Test results indicate that the Digistat Smart Central software complies with its predetermined specifications and the applicable guidance documents.

Performance Testing – Bench

The Digistat Smart Central was tested for performance in accordance with internal requirements and the following standards:

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

Test results indicate that the Digistat Smart Central complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Digistat Smart Central. The results of these activities demonstrate that the Digistat Smart Central is performs as well as the predicate devices.

Therefore, the Digistat Smart Central is considered substantially equivalent to the predicate devices.