510(k) Summary

NOV 2 0 2013

Submission Date:	30 September 2013
Submitter:	iSirona, LLC 430 West 5th Street, Suite 800 Panama City, FL 32401 USA
Submitter Contact:	Mr. Rabi Nur Phone: +1 (850) 250-3966 Email: Rabi.Nur@isirona.com
Application Correspondent:	Mr. Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	iSirona, LLC 430 West 5th Street, Suite 800 Panama City, FL 32401 USA
Trade Name:	iSirona Magellan
Common Name:	System, Network And Communication, Physiological Monitors
Classification Name:	System, Network And Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:

New iSirona Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
iSirona Magellan	K102974	Philips Medical Systems / Philips Emergin Event Management System

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Device Description:

iSirona Magellan, is an on-site messaging integration solution which forwards information about patient alarms and other medical-related events obtained from information sources such as patient monitors, ventilators, infusion pumps, etc. to the user. The user receives the information via selective remote devices such as centralized computer stations and mobile communication devices provided by third-party companies. iSirona Magellan utilizes the existing hospital network to process data and relay secondary notifications. It is not to be considered a primary alarming device.

iSirona Magellan connects to the information sources through wired ethernet connections which are part of the customer's infrastructure. The user configures iSirona Magellan to determine which information, including alarm notifications, is delivered to which users. iSirona Magellan then formats the data for wireless delivery to the centralized computer stations and mobile communication devices.

Intended Use:

The iSirona Magellan software solution provides healthcare professionals with supplemental information about patient alarms and other medical-related events. The product can route all or subsets of this information to selective remote devices such as centralized computer stations and mobile communication devices. Receipt of alarm messages or events by the centralized computer stations and/or mobile communication devices is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

Technology Comparison:

iSirona Magellan 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 primary medical device to display device	Yes	Same
Transmission of any alarm from a medical device	Yes	Same
Waveform data	Yes, static waveform data.	Same
Supported medical device inputs	Various manufacturers	HL7 compatible devices
Fixed display devices	Unknown	Yes, agnostic gateway
Mobile display devices	Pagers	Android devices running version 4.0.3 or greater

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Summary of Performance Testing:

Software Testing

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 standards and 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; and*
- *FDA guidance: Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 January 2005.*

Test results indicate that iSirona Magellan complies with its predetermined specifications, and applicable standards and guidance documents.

Performance Testing

iSirona Magellan was tested for performance in accordance with internal requirements.

Test results indicate that iSirona Magellan complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of iSirona Magellan. The results of these activities demonstrate that iSirona Magellan is safe and effective when used in accordance with its intended use and labeling.

Therefore, iSirona Magellan is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 20, 2013

iSirona, LLC
c/o Thomas Kroenke
Principal Consultant
Speed to Market, Inc.
PO Box 3018
Nederland, CO 80466

Re: K130707
Trade/Device Name: iSirona magellan
Regulation Number: 21 CFR 870.2300
Regulation Name: System, Network and Communication, Physiological Monitors
Regulatory Class: Class II (two)
Product Code: MSX
Dated: October 10, 2013
Received: October 11, 2013

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR 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.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -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): K

Device Name: iSirona Magellan

Indications for Use: The iSirona Magellan software solution provides healthcare professionals with supplemental information about patient alarms and other medical-related events. The product can route all or subsets of this information to selective remote devices such as centralized computer stations and mobile communication devices. Receipt of alarm messages or events by the centralized computer stations and/or mobile communication devices is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming 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 CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.11.20 10:29:54 -05'00'