K093422 P1/5

510(k) Summary

APR 29 2010

Date of Submission: ..... April 21, 2010

Device Trade Name: ..... Vital Sync™ System

Device Common Name: ..... Cardiac monitor (without alarms)

Device Classification Name: ..... Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Regulation and Code: ..... 21 CFR 870.2300, Product Code MWI

Submitted by: ..... Somanetics Corporation
2600 Troy Center Drive
Troy, MI 48084
Phone: 248-244-1400
Fax: 248-244-0978

Contact Person: ..... Ronald A. Widman
Vice President, Medical Affairs
248-244-1449

Predicate Device: ..... CentraView, ICU DataSystems, K033283

Device Description: ..... The Vital Sync™ System is a bedside data management system that receives historic digital data produced by primary external devices through device specific cables, accepts manual data entry, and displays and stores this information for review and archiving by healthcare professionals.

Accessories: ..... Serial Port Concentrator, 4 Port, Model 5000-SPC4
Serial Port Concentrator, 8 Port, Model 5000-SPC8
USB Cable, 5 meters, Model 5000-USB5
USB Cable, 1 meter, Model 5000-USB1
USB Extension Cable, 5 m, Model 5000-USBE5
Keyboard, Model 5000-KE
Mouse, Model 5000-MO
Roll Stand with Single Mount, Model 5000-RS
Roll Stand with Dual Mount, Model 5000-RS2
Desk Stand, Model 5000-DS
Serial Port Cable, 14 ft (4.27 m), Model SPAC-14
Serial Port Cable, 7 ft (2.13 m), Model SPAC-07
Serial Port Adapters, Models MA022-MA033
Printer w/ Isolation Transformer, Model 5000-PIK

	Advanced Clinical Tools Pkg, Model 5000 Advanced Clinical Tools Pkg, Model 5000-ACT
Intended Use:	The Vital Sync™ System is intended for display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. It is not intended for alarm notification, nor is it intended to control any of the independent bedside devices it is connected to. A listing of supported devices and displayed parameters is attached.
Technological Characteristics:	Intended use, operating principle, performance claims, and technological characteristics of the device, including design, materials, chemical composition and energy source are identical to the predicate device.
Performance Data:	Bench testing and verification and validation activities were performed to establish the performance, reliability and functionality of the Vital Sync System. Clinical testing was not required to establish substantial equivalence. Hazard analysis established the safety and system level testing and validation needed to demonstrate substantial equivalence. Testing modes included error handling, system faults, power cycling, consistency, recall, user interface, performance and maintenance procedures. Features tested include automated data capture, manual data entry, data formatting, report generation, trending, data backup and security. Additionally, the communication interface for each of the supported devices was stress-tested to ensure safety and compatibility with the Vital Sync System. Pass/fail criteria were established based on the published specifications of both the predicate and the current device. The results demonstrate substantial equivalence with the predicate device.
Conclusion Drawn from the Testing:	The conclusion drawn is that the device and the revised indications for use are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

Vital Sync System Displayed Parameters

Vital Sync Displayed Parameters

Amplitude Integrated EEG Left
Amplitude Integrated EEG Right
Anesthetic Agent
Air Temperature
Air Temperature Setting
Airway Temperature
Arterial Base Excess
Arterial Bicarbonate
Arterial pH
Arterial Temperature
Average Heart Rate
Axillary Temp
Bi-level Positive Airway Pressure
BIS
Bladder Temperature
Blood Temperature/Pulm. Artery Temperature
Body Surface Area
Bolus Cardiac Output
Bolus Cardiac Index
Brain PO2
Brain Temp
Calculated SO2
Cardiac Index
Cardiac Output
Stat Cardiac Index
Stat Cardiac Output
Cardioplegia Line Pressure
Central Venous Pressure
Cerebral Perfusion Pressure
Cerebral Blood Flow
Ch1 rSO2
Ch2 rSO2
Ch3 rSO2
Ch4 rSO2
Contractility Index
Contuous Cardiac Index
Continous Cardiac Output
Control Temp
Core Temperature
Coronary Sinus Pressure
Continuous Positive Airway Pressure
Delta Pressure
Dynamic Compliance
Ejection Fraction
Emboli 1
Emboli 2
Emboli 3
End Diastolic Volume
End Diastolic Volume Index
Stat End Diastolic Volume Index
Stat End Diastolic Volume
Exhaled Minute Volume
End Inspiratory Pressure
End Sysstolic Volume
End Sysstolic Volume Index
End Tidal CO2
Environement Temp
Esophageal Temperature
Exhaled Tidal Volume
Exhalation Time
Expired Positive Airway Pressure
Inspired Fraction of Oxygen
Infusate Temp
Flow Rate 1
Flow Rate 2
Flow Rate 3
Flow Velocity
Gastric pCO2
Heart Rate
Heater Output Percent
Heater Output Percent Setting
Hematocrit
Hemoglobin
High Inspired Pressure Setting
Humidity
Humidity Setting
Variation of Contractility Index
Inspired:Expired Ratio
Inspired CO2
Inspired O2 Setting
Insp Pos Air Pressure
Inspiratory Pressure
Inspiratory Resistance
Inspiratory Tidal Volume
Inspiratory Time
Intracranial Pressure
Diastolic Arterial Blood Pressure
Mean Arterial Blood Pressure
Systolic Arterial Blood Pressure
% Leak in Tidal Volume (Insp/Exp)
Left Atrial Pressure
Left Cardiac Work
Left Cardiac Work Index
Left Stroke Work

Vital Sync System Displayed Parameters (cont'd)

Vital Sync System Displayed Parameters (cont'd)

Left Stroke Work Index
Left Ventricular Ejection Time
Line Pressure
Mean Airway pressure
Mattress Temperature
Mattress Temperature Setting
Respiration Rate
Ventilation Mode
Myocardial Temperature
Nasopharyngeal Temperature
Nitric Oxide
Nitric Dioxide
Diastolic Cuff Blood Pressure
Mean Cuff Blood Pressure
Systolic Cuff Blood Pressure
Oxygen Consumption
Oxygen Extraction Index
Oral Temp
Arterial pCO2
Arterial pO2
Peak Flow
Plateau Time
Positive Pressure Duration
Potassium
Pressure Control
Pressure Limit
Pressure Sensitivity
Pressure Support
Pulmonary Capillary Wedge Pressure
Pulmonary Arterial Diastolic pressure
Pulmonary Arterial Mean Pressure
Pulmonary Arterial Systolic Pressure
Pulse Amplitude
Pulse Rate
Pump Flow
Venous pCO2
Venous pO2
Rate Pressure Product
Rectal Temperature
Right Ventricular Ejection fraction
Stat Right Ventricular Ejection fraction
Arterial SO2
Set Point Temperature
Skin Temperature
Skin Temperature Setting
Pulse SO2 1
Pulse SO2 2
Spectral Edge Frequency
Spontaneous Respiration rate
Static Compliance
ST Interval
Stat Stroke Volume Index
Stat Stroke Volume
Venous SO2
Oxygenator Sweep
Systolic Time Ratio
Thoracic Fluid Index
Tidal Volume Setting
Transcutaneous pCO2
Transcutaneous pO2
Tympanic Temperature
Venous pH
Venous Temperature
Volume Flow 1
Volume Flow 2
Volume Flow 3
Water Temperature
Weight

Vital Sync System Supported Devices (Listed by Company)

Atom Medical
Infa Warmer V505

Baxter Healthcare
AS 50
Colleague IP
FloGuard 6201
FloGuard 6301

Bird
VIP Gold/Sterling Ventilator

Cardiotronic/Osypka
Aesculon Noninvasive Cardiac Output

Cincinnati Sub-zero
Blanketrol II
Blanketrol III

Covidien/Tyco/Malinckrodt/Nellcor/Puritan Bennett
PB 840 Ventilator
N200 Pulse Oximeter
N295 Pulse Oximeter
N395 Pulse Oximeter
N595 Pulse Oximeter
InfantStar 500 Ventilator
InfantStar 950 Ventilator

Datex/Ohmeda
S/5 Patient Monitor

Draeger
Babylog 8000 Ventilator
Babylog 8000SC Ventilator
Evita Ventilator
Evita 2 Ventilator
Evita 4 Ventilator
Infinity Patient Monitor
SC7000
SC8000
SC9000XL

Edwards Life Sciences
Vigilance Hemodynamic Monitor
Vigilance II Hemodynamic Monitor
Vigileo Hemodynamic Monitor

General Electric
Dash 2000 Patient Monitor
Dash 3000 Patient Monitor
Dash 4000 Patient Monitor
Solar 8000i Patient Monitor
Solar 8000M Patient Monitor

Maquet/Siemens
Servo 300 Ventilator
Servo i Ventilator
Maquet Perfusion Pump System

Masimo
SET Radical-7 Pulse Oximeter
SET Radical-9 Pulse Oximeter

Mennen Medical
Horizon 2000 Patient Monitor

Philips/Agilent/Hewlett Packard
CMS 2001 Patient Monitor
V24 Patient Monitor
V26 Patient Monitor
MP5 Patient Monitor
MP20 Patient Monitor
MP40 Patient Monitor
MP50 Patient Monitor
MP60 Patient Monitor
MP70 Patient Monitor
MP80 Patient Monitor
MP90 Patient Monitor

Somanetics Corporation
INVOS 5100B Cerebral/Somatic Oximeter
INVOS 5100C Cerebral/Somatic Oximeter

Sorin Biomedica
Sorin S3 Perfusion Pump System
Sorin C5 Perfusion Pump System
Sorin S5 Perfusion Pump System
Sorin SIII Encore Perfusion Pump System

Viasys
Viasys Avea Ventilator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Somanetics Corporation
c/o Mr. Ronald A. Widman
Vice President, Medical Affairs
2600 Troy Center Drive
Troy, MI 48084

APR 29 2010

Re: K093422
Device Name: Vital Sync™ System
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II (Two)
Product Code: MWI
Dated: April 21, 2010
Received: April 22, 2010

Dear Mr. Widman:

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

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.htm for 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,

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): K093422

Device Name: Somanetics Vital Sync™ System and Accessories

Indications For Use:

The Vital Sync™ System is intended for display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. It is not intended for alarm notification, nor is it intended to control any of the independent bedside devices it is connected to.

Vital Sync System displayed parameters are listed on the following pages.

Prescription Use X (Part 21 CFR 801 subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093422

K093422

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Water Temperature
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