



Food and Drug Administration
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May 5, 2016

ICU Medical Inc.
Natalie Hepworth
Regulatory Affairs Associate
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San Clemente, California 92673

Re: K152006

Trade/Device Name: Cogent™ Hemodynamic Monitoring System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG, DQA
Dated: March 31, 2016
Received: April 1, 2016

Dear Natalie Hepworth:

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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Bram D. Zuckerman -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152006

Device Name

Cogent™ Hemodynamic Monitoring System

Indications for Use (Describe)

- The Cogent™ Hemodynamic Monitoring System (HMS) is intended for patients for whom the monitoring of continuous cardiac output and calculated hemodynamic parameters is indicated for diagnostic and prognostic evaluation by a clinician. Suitability for use on a patient is up to the physician's judgment and the diameter of the catheter to be used.
- The target population includes patients for whom hemodynamic monitoring will improve clinical care. The target populations are identical to those for the predicate devices and include:
 - o Critical Care Patients
 - o Trauma Patients
 - o Cardiac Surgery Patients
- The Cogent™ HMS is intended for use with ICU Medical pulmonary artery catheters and central venous oximetry catheters, and with ICU Medical Cogent™ sensors.
- The Cogent™ HMS is intended to measure and calculate venous oxygen saturation in patients.
- PulseCO functionality is limited to adult patients
- The intended environment for use is the hospital including Critical Care Units (such as Medical, Surgical, and Coronary), Trauma and Accident Emergency Units, Post Anesthesia Care Units, Operating Rooms, and Cardiac Catheterization labs.
- The Cogent™ HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and accident emergency units, coronary and intensive care units and cardiac catheterization laboratories.
- The Cogent™ HMS is restricted to one patient at a time.

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.

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30 March 2016

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

1 Submitter

ICU Medical Inc.

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2 Device

Name of Device:	Cogent™ Hemodynamic Monitoring System
Common or usual name:	Cardiac output and oximetry monitor
Classification name:	Single-functioned, preprogrammed diagnostic computer (21 CFR §870.1435) and Oximeter (21 CFR §870.2700)
Regulatory Class:	II
Product Code:	DXG and DQA

3 Predicate Devices

Primary predicate: Abbott Q2 Plus SO₂/Continuous Cardiac Output Computer, K021874

Secondary predicate: LiDCORapid Hemodynamic Monitor, K122247

These predicates have not been subjected to a design-related recall.

4 Device Description

The Cogent™ HMS system is designed to compute and display cardiac and oximetry parameters relevant to patient care in the hospital acute care areas including Intensive Care Units and the Operating Room. Parameters include cardiac output and blood oxygen saturation levels, as well as other derived hemodynamic parameters. Measurements are obtained through ICU Medical pulmonary artery and central venous oximetry catheters, and ICU Medical CardioFlo™ sensors.

Input data for derived parameters may be keyed in by a clinician or may be obtained from a bedside monitor.

The Cogent™ HMS provides the following functions:

- monitors patient cardiac output continuously, using continuous thermodilution, and intermittently,

using bolus thermodilution;

- monitors cardiac output continuously using Pulse Power analysis on an arterial pressure waveform;
- monitors venous oxygen saturation by measuring the reflectance spectrum of the blood; and
- provides a general-purpose interface to the analog input/output channels of other monitoring devices.

The Cogent™ HMS consists of a base unit (patient interface module, PIM), a dedicated touch-screen display unit (user interface module, UIM) which allows for patient monitoring remotely (up to 50 feet), and the associated cables. The modules communicate with each other in docked, tethered (wired) or wireless mode. A physically separate optical module (OpMod) connects with an oximetry catheter.

The Cogent™ HMS is designed for compatibility with PA catheters via connection to existing patient cables, i.e. unchanged cables as supplied with the primary predicate Q2 Plus.

For the purpose of PulseCO™ data acquisition, the Cogent™ HMS is designed for compatibility with the CardioFlo™ sensor and the new CardioFlo™ reusable cable.

In order to calculate blood oxygen saturation, the Cogent™ HMS is designed for compatibility with the existing optical module, its existing integrated cable and its associated compatible PA and oximetry catheters.

5 Indications for Use

- The Cogent™ Hemodynamic Monitoring System (HMS) is intended for patients for whom the monitoring of continuous cardiac output and calculated hemodynamic parameters is indicated for diagnostic and prognostic evaluation by a clinician. Suitability for use on a patient is up to the physician's judgment and the diameter of the catheter to be used.
- The target population includes patients for whom hemodynamic monitoring will improve clinical care. The target populations include:
 - Critical Care Patients
 - Trauma Patients
 - Cardiac Surgery Patients
- The Cogent™ HMS is intended for use with ICU Medical pulmonary artery catheters and central venous oximetry catheters, and with ICU Medical CardioFlo™ sensors.
- The Cogent™ HMS is intended to measure and calculate venous oxygen saturation in patients.
- PulseCO functionality is limited to adult patients
- The intended environment of use is the hospital including Critical Care Units (such as Medical, Surgical, and Coronary), Trauma and Accident Emergency Units, Post Anesthesia Care Units, Operating Rooms, and Cardiac Catheterization labs.
- Cogent™ HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and accident emergency units, coronary and intensive care units and cardiac catheterization laboratories.
- Use of the Cogent™ HMS is restricted to one patient at a time.

The Indications for Use statement for the Cogent™ HMS device is not worded identically to the predicate devices; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the subject and predicate devices have the same intended use for monitoring continuous cardiac output and derived hemodynamic parameters and to measure and calculate venous oxygen saturation.

6 Comparison of Technological Characteristics with the Predicate Device

At a high level, the subject and primary predicate devices are based on the following same technological elements:

- Measurement algorithm for CCO: Continuous Cardiac Output measured using continuous thermodilution.
- Measurement algorithm for TdCO: Thermodilution Cardiac Output; intermittent cardiac output measured using bolus thermodilution.
- Measurement algorithm for SO₂: blood oxygen saturation.

The following technological differences exist between the subject and primary predicate devices:

- The Cogent™ HMS has the additional functionality of continuous monitoring of patient cardiac output using the PulseCO analysis of the arterial blood pressure trace. The algorithm used for this additional functionality is the PulseCO algorithm which is used in the secondary predicate device, the LiDCOrapid Hemodynamic Monitor (K122247).
- The Cogent™ HMS includes an algorithm that calculates heart rate from an analog ECG input.
- The electronic design of the Cogent™ HMS has been upgraded from the primary predicate device to bring it up to current technological standards, e.g. PCBA technology utilizing SMDs and lead-free soldering and the integrated display UIM replacing the built-in screen.

7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The Cogent™ HMS is not considered tissue contacting therefore no biocompatibility testing was performed. Tissue contacting accessories such as catheters are covered under separate 510(k) submissions.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Cogent™ HMS device, consisting of the PIM unit, the UIM display unit, the Optical Module and associated cables. The system complies with the IEC 60601-1, IEC 60601-1-8, IEC 60601-2-34 (to the extent applicable), IEC 60601-2-49 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

Simulated Use Testing

Bench studies were conducted in simulated use environments to validate the safety and efficacy of the Cogent™ HMS.

- Testing of the CCO, TdCO and SO₂ algorithms using bench simulation.
- Testing of the PulseCO algorithm using the same simulated physiological data set as was used for the secondary predicate device.

These studies demonstrate that the measurement performance of the Cogent™ HMS device is equivalent to that of the predicate devices, the Q2 Plus and the LiDCOrapid V2 Hemodynamic Monitor.

Animal Study

The animal study involved 5 pigs. After obtaining venous access, proper positioning of the catheter per standard clinical procedure and connecting the catheter to a Cogent™ HMS, cardiac output and blood oxygen saturation were varied in a series of steps from the animal's baseline values using pharmacological interventions and changes in ventilator settings as necessary. CCO, TdCO, and SvO₂ values were acquired and compared against measurements from accepted reference devices.

This study demonstrated that the measurement performance of the Cogent™ HMS device is equivalent to the predicate device, the Q2 Plus.

Clinical Studies

No clinical performance testing was required to demonstrate device safety and effectiveness.

8 Conclusions

The non-clinical data support the safety of the device, and the hardware and software verification and validation demonstrate that the Cogent™ HMS should perform as intended in the specified use conditions. The bench performance data and animal study demonstrate that the Cogent™ HMS performs comparably to the primary predicate device that is currently marketed for the same intended use, and to the secondary predicate device for the additional feature of the PulseCO algorithm.

Hardware testing carried out for the Cogent™ HMS indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and that it functions equivalently to the predicate device. The device meets standard requirements for electrical safety and electromagnetic compatibility.

This information indicates that the Cogent™ HMS is equivalent to the predicate devices in terms of device safety and effectiveness.