December 20, 2023

ICU Medical
Diane Stockman
Senior Regulatory Associate, Global Regulatory
915 Calle Amanecer
San Clemente, California 92673

Re: K232048
Trade/Device Name: Cogent™ Hemodynamic Monitoring System (HMS)
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG, DQA
Dated: December 5, 2023
Received: December 8, 2023

Dear Diane Stockman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232048

Device Name
Cogent™ Hemodynamic Monitoring System (HMS)

Indications for Use *(Describe)*

The Cogent HMS is intended for patients for whom the monitoring of CCO and calculated hemodynamic parameters is indicated for diagnostic and prognostic evaluation by a clinician. 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.

Target Population -
The target populations are critical care patients, trauma patients, and cardiac surgery patients. The Cogent HMS is restricted to one patient at a time, and the PulseCO functionality is limited to adult patients. There are no specific contraindications for the instrument. Suitability for use on a patient is up to the physician's judgment. The physician shall also decide on the diameter of the catheter to be used in conjunction with the Cogent HMS.

Environments for Use -
The Cogent HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and emergency units, coronary and intensive care units, and cardiac catheterization laboratories. The intended environment for use is the hospital, including the critical care units (i.e. medical, surgical, coronary), trauma and accident emergency units, post-anesthesia care units, operating rooms, and cardiac catheterization labs.

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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510(k) Summary

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21CFR 870.1435 for the Cogent™ Hemodynamic Monitoring System (HMS) is provided below:

I. Submitter Information

Company Name	ICU Medical, Inc.
Company Address	951 Calle Amanecer, San Clemente, CA 92673
Establishment Registration Number	2025816
Application Correspondent Name & Contact	Diane Stockman, Global Regulatory Affairs 224-706-2521
Date prepared	December 19, 2023

II. Device Information

Trade or proprietary name	Cogent™ Hemodynamic Monitoring System (HMS)
Common or usual name	Hemodynamic Monitor
Regulation Name	Computer, Diagnostic, Pre-Programmed, Single-Function
Classification / Reason	Class II per 21 CFR 870.1435
Product Code(s)	DXG - Computer, Diagnostic, Pre-Programmed, Single-Function; DQA - Oximeter
Legally marketed device(s) to which equivalence s claimed	K152006, Cogent™ Hemodynamic Monitoring System (ICU Medical) with software version 1.1.8

III. Reason for 510(k) Submission

The purpose of this submission is to introduce new design features including an update to the Operating System from Windows 7 to Windows 10, enhancements to the user interface, software updates (from version 1.1.8 to 1.4.0) which includes feature enhancements and addresses known anomalies associated with the Windows transition, and minor hardware changes for obsolescence of components.

The obsolescence of the Windows 7 operating system (by Microsoft) and board processors are driving the need to upgrade the Cogent Hemodynamic Monitoring System (HMS) hardware and software in both the Power Interface Module (PIM) and the User Interface Module (UIM).

In addition, this submission provides a description of non-substantial changes made since the Cogent HMS initial clearance (under K152006) which were assessed and found to not impact the cleared device design, intended use, or risk levels. These changes were implemented in both the

Windows 7 (list number 58400-000) and Windows 10 (list number 58400-200) configurations of the Cogent HMS device.

The fundamental technology, device parameters, mode of operation, and intended use of the Cogent HMS remain unchanged from the Predicate Device.

IV. Device Description

The Cogent HMS 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. Monitoring parameters include cardiac output and blood oxygen saturation levels, as well as other derived hemodynamic parameters. Measurements are obtained through the compatible 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 (CCO) using continuous thermodilution (TdCO), and intermittently, using bolus thermodilution (Bolus CO);
- monitors continuous cardiac output (CCO) using pulse power analysis on an arterial pressure waveform;
- monitors venous oxygen saturation (SvO2) 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 or PIM);
- a dedicated touch-screen display unit (user interface module or UIM) which allows for patient monitoring remotely (up to 50 feet); and
- associated cables

The PIM and UIM modules communicate with each other in docked, tethered (wired) or wireless mode.

The Cogent HMS is designed for compatibility with:

- ICU Medical Pulmonary Artery (PA) catheters via connection to cardiac output patient cables for the purposes of thermodilution cardiac output measurement.
- ICU Medical CardioFlo sensor and the CardioFlo reusable cable for the purpose of pulse power cardiac output measurement.

- ICU Medical optical module or OpMod reusable cable, and its associated compatible ICU Medical PA and Central Venous oximetry catheters to calculate blood oxygen saturation.

V. Indications for Use

The Cogent HMS is intended for patients for whom the monitoring of CCO and calculated hemodynamic parameters is indicated for diagnostic and prognostic evaluation by a clinician. 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.

Target Population

The target populations are critical care patients, trauma patients, and cardiac surgery patients. The Cogent HMS is restricted to one patient at a time, and the PulseCO functionality is limited to adult patients. There are no specific contraindications for the instrument. Suitability for use on a patient is up to the physician's judgment. The physician shall also decide on the diameter of the catheter to be used in conjunction with the Cogent HMS.

Environments for Use

The Cogent HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and emergency units, coronary and intensive care units, and cardiac catheterization laboratories. The intended environment for use is the hospital, including the critical care units (i.e. medical, surgical, coronary), trauma and accident emergency units, post-anesthesia care units, operating rooms, and cardiac catheterization labs.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristics	***Subject Device*** ICU Medical Cogent™ HMS List Number 58400-200	***Predicate Device (K152006)*** ICU Medical Cogent™ HMS List Number 58400-000	**Comparison**
Device Name	Cogent™ Hemodynamic Monitoring System or Cogent HMS	Cogent™ Hemodynamic Monitoring System or Cogent HMS	Same
Operating System	Windows 10 OS	Windows 7 OS	Updated
Software version	version 1.4.0	version 1.1.8	Updated
Product Code	DXG - Computer, Diagnostic, Pre-Programmed, Single-Function (primary) & DQA – Oximeter (secondary)	DXG - Computer, Diagnostic, Pre-Programmed, Single-Function (primary) & DQA – Oximeter (secondary)	Same

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristics	*Subject Device* ICU Medical Cogent™ HMS List Number 58400-200	*Predicate Device (K152006)* ICU Medical Cogent™ HMS List Number 58400-000	Comparison
Intended Use/ Indications for Use	The Cogent HMS is intended for patients for whom the monitoring of CCO and calculated hemodynamic parameters is indicated for diagnostic and prognostic evaluation by a clinician. 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. Target Population - The target populations are critical care patients, trauma patients, and cardiac surgery patients. The Cogent HMS is restricted to one patient at a time, and the PulseCO functionality is limited to adult patients. There are no specific contraindications for the instrument. Suitability for use on a patient is up to the physician's judgment. The physician shall also decide on the diameter of the catheter to be used in conjunction with the Cogent HMS. Environments for Use - The Cogent HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and emergency units, coronary and intensive care units, and cardiac catheterization laboratories. The intended environment for use is the hospital, including the critical care units (i.e. medical, surgical, coronary), trauma and accident emergency units, post-anesthesia care units, operating rooms, and cardiac catheterization labs.	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.	Similar The statement was reworded for clarity only.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	***Subject Device*** ICU Medical Cogent™ HMS List Number 58400-200	***Predicate Device (K152006)*** ICU Medical Cogent™ HMS List Number 58400-000	**Comparison**
Target Population	The target populations are critical care patients, trauma patients, and cardiac surgery patients. The Cogent HMS is restricted to one patient at a time, and the PulseCO functionality is limited to adult patients. There are no specific contraindications for the instrument. Suitability for use on a patient is up to the physician's judgment. The physician shall also decide on the diameter of the catheter to be used in conjunction with the Cogent HMS.	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	Similar Reworded for added clarity only.
Environments for Use	The Cogent HMS is intended to be used by trained and qualified individuals in medical and surgical intensive care units, operating rooms, trauma and emergency units, coronary and intensive care units, and cardiac catheterization laboratories. The intended environment for use is the hospital, including the critical care units (i.e. medical, surgical, coronary), trauma and accident emergency units, post-anesthesia care units, operating rooms, and cardiac catheterization labs.	• 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.	Similar Reworded for added clarity only.
Principle of Operation	A monitoring system to display clinical measurements of a patient's hemodynamic (cardiovascular) function when connected to a catheter or sensor attached to a patient.	A monitoring system to display clinical measurements of a patient's hemodynamic (cardiovascular) function when connected to a catheter or sensor attached to a patient.	Same
Mechanism/Mode of Action	Displays entered, measured, and derived hemodynamic monitoring parameters via device interconnection with compatible cable, optical module, and/or bedside monitor to a compatible catheter or pressure sensor (attached to the patient).	Displays entered, measured, and derived hemodynamic monitoring parameters via device interconnection with compatible cable, optical module, and/or bedside monitor to a compatible catheter or pressure sensor (attached to the patient).	Same

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	***Subject Device*** ICU Medical Cogent™ HMS List Number 58400-200	***Predicate Device (K152006)*** ICU Medical Cogent™ HMS List Number 58400-000	**Comparison**
Displayed parameters	• CCO using continuous thermodilution • CCO using arterial pressure waveform analysis • Intermittent CO using bolus thermodilution • Venous oxygen saturation (SvO2) using reflectance spectrophotometry • Data via interface to other bedside monitoring devices	• CCO using continuous thermodilution • CCO using arterial pressure waveform analysis • Intermittent CO using bolus thermodilution • Venous oxygen saturation (SvO2) using reflectance spectrophotometry • Data via interface to other bedside monitoring devices	Same
Measurement Specifications	• Oxygen Saturation: o range: 10% to 100% o repeatability: delta ≤ 2% for a mean in the range of 40% to 100% • Blood Temperature o range: 77°F to 107.6°F (25°C to 42°C) o accuracy: ± 0.54°F (± 0.3°C) for a measurement at 98.6°F (37°C) • CCO (using PA catheter) o range: 1 LPM through 20 LPM o repeatability: CV ≤ 3% using a flow simulator o temperature range: 86°F to 104°F (30°C to 40°C) CCO measurement range • Bolus CO (Thermodilution) o range: 0.1 LPM through 20 LPM o repeatability: CV ≤ 2% averaged over 20 measurements using electronically generated data • CCO (using CardioFlo sensor) o range: 1 LPM through 20 LPM o repeatability: CV ± 6% or 0.1 LPM, whichever is greater, when simulated with patient-recorded signal • Heart Rate using ECG analog o Range: 30 bpm through 200 bpm • Heater output o 7.5 Watts max, 6.0 Watts nominal • External values displayed o SpO2, MAP, CVP, HR • SpO2 display range: 10 to 100% • Blood temp. display range o 60.8°F to 122°F (16°C to 50°C)	• Oxygen Saturation: o range: 10% to 100% o repeatability: delta ≤ 2% for a mean in the range of 40% to 100% • Blood Temperature o range: 77°F to 107.6°F (25°C to 42°C) o accuracy: ± 0.54°F (± 0.3°C) for a measurement at 98.6°F (37°C) • CCO (using PA catheter) o range: 1 LPM through 20 LPM o repeatability: CV ≤ 3% using a flow simulator o temperature range: 86°F to 104°F (30°C to 40°C) CCO measurement range • Bolus CO (Thermodilution) o range: 0.1 LPM through 20 LPM o repeatability: CV ≤ 2% averaged over 20 measurements using electronically generated data • CCO (using CardioFlo sensor) o range: 1 LPM through 20 LPM o repeatability: CV ± 6% or 0.1 LPM, whichever is greater, when simulated with patient-recorded signal • Heart Rate using ECG analog o Range: 30 bpm through 200 bpm • Heater output o 7.5 Watts max, 6.0 Watts nominal • External values displayed o SpO2, MAP, CVP, HR • SpO2 display range: 10 to 100% • Blood temp. display range o 60.8°F to 122°F (16°C to 50°C)	Same

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	***Subject Device*** ICU Medical Cogent™ HMS List Number 58400-200	***Predicate Device (K152006)*** ICU Medical Cogent™ HMS List Number 58400-000	**Comparison**
Compatibility – Catheters and sensors	Compatible with currently marketed ICU Medical catheters and pressure sensors via patient interface cables.	Compatible with currently marketed ICU Medical catheters and pressure sensors via patient interface cables.	Same
Materials of Construction	• Base Unit (PIM): Polycarbonate – Siloxane Copolymer SABIC, LEXAN Copolymer EXL9330-BK1A068 • Display Unit (UIM): Polycarbonate -Sabic (E45329) Cycoloy C2950	• Base Unit (PIM): Polycarbonate – Siloxane Copolymer SABIC, LEXAN Copolymer EXL9330-BK1A068 • Display Unit (UIM): Polycarbonate -Sabic (E45329) Cycoloy C2950	Same
Physical and Mechanical Specifications			
Display type:	Color LCD touch screen	Color LCD touch screen	Same
Memory:	Stores 4 patient records up to 72 hours each	Stores 4 patient records up to 72 hours each	Same
Dimensions:	11” x 10” x 7” (27.9 cm x 25.4 cm x 17.8 cm)	11” x 10” x 7” (27.9 cm x 25.4 cm x 17.8 cm)	Same
Weight:	11 lbs (4.9 kg)	10lbs excluding power cables (11 lbs (4.9 kg) includes cables)	Same
Battery:	Li-ion Rechargeable	Li-ion Rechargeable	Same
Environmental Specifications			
Operating temperature:	50°F to 98.6°F (10°C to 37°C)	50°F to 98.6°F (10°C to 37°C)	Same
Operating humidity:	10% to 90% (noncondensing)	10% to 90% (noncondensing)	Same
Operating altitude:	0 to 8,000 feet (0 to 3,000 m) above sea level	0 to 8,000 feet (0 to 3,000 m) above sea level	Same
Atmospheric pressure:	70 to 104 kPa	70 to 104 kPa	Same
Storage temperature:	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)	Same
Storage humidity:	10% to 90% noncondensing	10% to 90% noncondensing	Same
Technical Specifications			
Operating power range	90 to 130 VAC Single Phase, 2.0A RMS, 47-63Hz, 210 to 254 VAC Single Phase, 1.0A RMS, 47-63Hz	90 to 130 VAC Single Phase, 2.0A RMS, 47-63Hz, 210 to 254 VAC Single Phase, 1.0A RMS, 47-63Hz	Same
Alarm audio range	Off, and 45 to 85 dB at 0.5 meters	Off, and 45 to 85 dB at 0.5 meters	Same
Power Interface Module (PIM)			
Port connections	• Analog input/output: ECG; 1-3 inputs; 1-2 outputs • Digital: RS-232 ports 1-2; ethernet; UIM tether port	• Analog input/output: ECG; 1-3 inputs; 1-2 outputs • Digital: RS-232 ports 1-2; ethernet; UIM tether port	Same
User Interface Module (UIM)			
Alarm tones	High-priority; Low-priority; Informational	High-priority; Low-priority; Informational	Same

VII. Comparison Summary

The modified Cogent HMS (with Windows 10 OS, software version 1.4.0, and hardware updates) is designed with the same fundamental technology, mode of operation, intended use/indications for use, mechanical design, and material of construction as the predicate Cogent HMS (cleared under K152006).

The differences between the subject device compared to the predicate device are the following:

- Updated operating system from Windows 7 to Windows 10 due to Windows 7 obsolescence (by Microsoft).
- Updated software version from 1.1.8 to 1.4.0 to support Windows transition and to address known anomalies.
- Modified software and hardware (power management board; display) in Power Interface Module (PIM) and User Interface Module (UIM) to support Windows transition and parts obsolescence.

In addition, modifications were made to the Cogent HMS compatible ICU Medical OpMod Cable in software revision from 3.1 to 3.2, and a like-for-like change to the detector component and epoxy material for improved manufacturability. These changes do not affect the cleared device's functionality or performance, and no new risks or modifications to existing risks were introduced.

VIII. Summary of Simulated Use (Non-Clinical) Testing

To demonstrate substantial equivalence between the subject device and the predicate device the following non-clinical tests were performed:

- **Biocompatibility**
  The Cogent HMS is not considered to have direct or indirect patient or tissue contact, therefore no biocompatibility testing was performed or required. The patient contacting accessories such as catheters and sensors are out of scope for this submission and are 510(k) cleared under separate premarket notifications.

- **Simulated Use - System Bench Testing**
  Bench studies were conducted in simulated use environments to verify and validate the safety and efficacy of the Cogent HMS. These studies demonstrate that the measurement performance of the subject device is equivalent to that of the predicate device.
  - PulseCO Algorithm Validation
  - Bolus CO Algorithm In Vitro Validation
  - SO2 Algorithm In Vitro Validation
  - CCO Algorithm In Vitro Validation
  - Cogent System Software Validation

- **Software Verification and Validation Testing**
  Software verification and validation testing were successfully conducted in accordance with ICU Medical Software Verification and Validation process per IEC 62304 and 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 the subject device is considered equivalent to the predicate device, 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.

- **Electrical Safety and Electromagnetic Compatibility**

Electrical Safety per IEC 60601-1 and Electromagnetic Compatibility (EMC) per IEC 60601-1-2 testing were conducted at an Independent Nationally Recognized Testing Laboratory (NRTL). Results conclude the subject device complies with requirements per these standards.

- **Cybersecurity**
  Cybersecurity testing was performed and concludes that the system is effective in addressing cybersecurity threats. FDA Cybersecurity Guidance followed during development include Content of Premarket Submissions for Management of Cybersecurity, issued October 2, 2014 and Post-market Management of Cybersecurity in Medical Devices, issued December 28, 2016.

- **Risk Management**
  Risk management activities have been incorporated into the design updates in accordance with ISO 14971:2019 and have been tested for correct implementation and effectiveness as part of verification and validation.

- **Human Factors/Animal/ Clinical Studies**
  No new human factors, animal, and/or clinical studies were conducted as was determined not required to demonstrate device safety and effectiveness for the subject device. No changes were made to the User Interface and the device maintained the same screen layout, menu selections layout and system navigation for added features/functions.

IX. Conclusion

The modified Cogent HMS (including new Operating System, software and 'like for like' hardware updates) meets functional performance and intended use claims as described in the device labeling. The modifications to the subject device consider the same questions of safety and effectiveness as the predicate device, and there are no different questions of safety and effectiveness introduced.

The results of software, electrical safety, system verification and validation testing conclude that the Cogent HMS with Windows 10 Operating System, software version 1.4.0, and hardware modifications is safe and effective for intended users, uses, and use environments, and that no clinical investigation or further testing is needed. The methods and results described in the validation reports support this conclusion. The results of these tests have demonstrated the overall safety of the subject device and ultimately supports a substantial equivalence determination of the modified Cogent HMS to the predicate device cleared under K152006.