April 25, 2024

Terumo Cardiovascular Systems Corporation
Rahul Chinkeri
Senior Regulatory Affairs Specialist
6200 Jackson Rd
Ann Arbor, Michigan 48103

Re: K234065
Trade/Device Name: CDI OneView Monitoring System
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II
Product Code: DRY
Dated: March 22, 2024
Received: March 22, 2024

Dear Rahul Chinkeri:

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234065

Device Name

CDI OneView Monitoring System

Indications for Use *(Describe)*

The CDI OneView Monitoring System is a patient parameter monitoring system to be used on a single patient during cardiopulmonary bypass procedures. By measurement or acquisition from other devices, it displays and outputs information to provide continuous, in-line monitoring of various patient parameters contained within the extracorporeal perfusion circuit and patient. The following parameters are available, based on configuration:

- Potential of Hydrogen (pH)
- Partial Pressure of Carbon Dioxide (pCO2)
- Partial Pressure of Oxygen (pO2)
- Potassium Ion (K+)
- Oxygen Saturation (SO2)
- Hematocrit (HCT)
- Hemoglobin (Hgb)
- Blood Flow Rate ($\dot{Q}$)
- Cardiac Index (CI)
- Base Excess (BE)
- Bicarbonate ($HCO3^-$)
- Oxygen Consumption (VO2)
- Indexed Oxygen Consumption (VO2i)
- Oxygen Delivery (DO2)
- Indexed Oxygen Delivery (DO2i)
- Cerebral Regional Oxygen Saturation (rSO2)
- Oxygen Extraction Ratio (O2ER)
- Body Surface Area (BSA)
- Shunt Sensor Temperature

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CDI OneView™ Monitoring System
510(k) Summary

This section is prepared in accordance with 21 CFR Part 807.92

I. General Information

Submitters Name and Address:	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor, MI 48103
Name of the Contact Person:	Rahul Reddy Chinkeri, Senior RA Specialist
Phone Number:	Tel: +1 734-822-1877
Email:	rahul.chinkeri@terumomedical.com
Establishment Registration:	1828100
Date Prepared:	22 December 2023

II. Device Information

Trade Name:	CDI OneView™ Monitoring System
Common/Generic Name:	Extracorporeal Blood Gas Monitor
Classification Name:	Monitor, Blood-gas, Cardiopulmonary Bypass
Device Class:	Class II
Classification Panel:	74 Cardiovascular
Regulation Number:	21 CFR §870.4330
Product Code(s):	DRY

III. Predicate Device

CDI Blood Parameter Monitoring System 550, cleared under K182110.

IV. Device Description

The CDI OneView Monitoring System is an AC-powered (battery back-up) microprocessor-based device used with the following components/accessories:

- Core: Core Processing Unit, all other elements connect to the Core
- Display: Touchscreen display with cable
- HSAT Probe: Hematocrit/Saturation probe with cable, interfaces with disposable Cuvette(s)
- BPM Probe: Blood Parameter Module with cable, interfaces with disposable Shunt Sensor

- Calibrator: Gas calibrator for BPM/Shunt Sensor with cable, interfaces with disposable gas bottles
- Flow Module & Sensor: Flow sensor connected to an external interface module with cable.
- HLM External Device Module: Heart Lung Machine (HLM) interfacing module and cable
- DMS External Device Module: Data output for data management system (DMS) interfacing module and cable
- rSO2 External Device Module: Cerebral Oximetry device interfacing module and cable
- Mounting accessories: Different mounting features are used to securely mount elements of the system on an HLM pole during a cardiopulmonary bypass (CPB) case.
- Disposable accessories: The CDI OneView Monitoring System hardware connects to disposable accessories which are in-line with the extracorporeal circuit. The BPM probe is attached to Shunt Sensors, the HSAT probe is attached to Cuvette(s) during a CPB case for blood parameters measurement during monitoring. Disposable Gas Bottles (Gas 1 & Gas 2) are used with the Calibrator.

The CDI OneView Monitoring System uses the following measurement technologies:

- Optical fluorescence technology to measure partial pressure of oxygen and carbon dioxide, pH and potassium ion concentration.
- Optical reflectance technology to measure oxygen saturation, hematocrit, and hemoglobin within the blood.
- Thermistor (resistive) sensing technology to measure blood temperature.
- Non-invasive acoustical sensing technology to measure blood flowrate.

The CDI OneView Monitoring System measures blood parameters in real time by utilizing a microprocessor-based core, electro-optics modules (i.e., BPM and H/S probe), flow probe (includes flow module and flow sensor), fluorescence chemistry technology, optical reflectance technology and non-invasive acoustical sensing technology. The electro-optics modules connect the core to the disposables (i.e., shunt sensor or cuvette) which are inserted into the extracorporeal circuit. The flow module connects the core to the flow sensor that use clamp-on mechanism to fit around tubing of the extracorporeal circuit. Light is emitted from the modules, optical responses from the blood and the Ultrasonic/acoustical generated signal measurements via the sensor(s) are measured by the core. The blood parameters are measured or calculated by the CDI OneView Processing Core in real time and displayed to the user via a Touchscreen Display.

The following blood parameters in Table 1 below are measured or calculated by the CDI OneView Processing Core in real time and displayed to the user via Touchscreen Display.

Measured	Calculated
– pH – Partial Pressure of Carbon Dioxide (PCO_2) – Partial Pressure of Oxygen (PO_2) – Potassium (K+) – Shunt Temperature – Oxygen Saturation (SO_2) – Hematocrit (HCT) – Hemoglobin (Hgb) – Blood Flowrate (Q)	– Base Excess (BE) – Bicarbonate (HCO_3) – Oxygen Saturation (calculated when measured is not available) – Oxygen Consumption (VO_2) – Indexed Oxygen Consumption (VO_2i) – Oxygen Delivery (DO_2) – Indexed Oxygen Delivery (DO_2i) – Oxygen Extraction Ration (O_2ER) – Cardiac Index (CI)

Table 1: CDI OneView Monitoring System Measured and Calculated Parameters

The CDI OneView Monitoring System records blood parameter values, status, and event information during a case.

The CDI OneView Monitoring System acquires Cerebral regional oxygen saturation (rSO_2) and blood flow (if not using flow probe) from external devices and displays these parameters.

The CDI OneView Monitoring System saves patient case record data into the system memory or data can be streamed into institution database via a Data Management System connected to the system.

Additionally, a user is able to export one or multiple case data stored on the device memory via a USB port located on the Touchscreen Display.

V. Indications for Use

The CDI OneView Monitoring System is a patient parameter monitoring system to be used on a single patient during cardiopulmonary bypass procedures. By measurement or acquisition from other devices, it displays and outputs information to provide continuous, in-line monitoring of various patient parameters contained within the extracorporeal perfusion circuit and patient. The following parameters are available, based on configuration:

- Potential of Hydrogen pH
- Partial Pressure of Carbon Dioxide (pCO_2)
- Partial Pressure of Oxygen (pO_2)

- Potassium Ion (K+)
- Oxygen Saturation (SO_2)
- Hematocrit (HCT)
- Hemoglobin (Hgb)
- Blood Flowrate (Q)
- Cardiac Index (CI)
- Base Excess (BE)
- Bicarbonate (HCO_3-)
- Oxygen Consumption (VO_2)
- Indexed Oxygen Consumption (VO_2i)
- Oxygen Delivery (DO2)
- Indexed Oxygen Delivery (DO_2i)
- Cerebral regional oxygen saturation (rSO_2)
- Oxygen Extraction Ratio (O_2ER)
- Body Surface Area (BSA)
- Shunt Sensor Temperature

VI. Comparison of Intended Use/Indications to the Predicate Device

The subject and the predicate device have the same intended use as both devices are intended to provide continuous, in-line monitoring of various patient parameters contained within the extracorporeal perfusion circuit and patient during cardiopulmonary bypass procedures.

The subject device indication statement has following changes:

- Blood Flow Rate (Q) as new measured parameter.
- Oxygen Extraction Ration (O_2ER) and Cardiac Index (CI) as additional calculated parameters.
- Cerebral regional oxygen saturation as additional acquired parameter acquired from Cerebral Oximetry Device.

These differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

These changes are best analyzed through potential differences in Technological Characteristics that are summarized in section below.

VII. Comparison of Technological Characteristics

Subject Device- CDI OneView Monitoring System Functions	Predicate Device- CDI 550 (K182110) Functions	Difference in technological characteristic between subject device and predicate
Measured data		
Partial Pressure of Oxygen	Partial Pressure of Oxygen	Same

Subject Device- CDI OneView Monitoring System Functions	Predicate Device- CDI 550 (K182110) Functions	Difference in technological characteristic between subject device and predicate
Partial Pressure of Carbon Dioxide	Partial Pressure of Carbon Dioxide	Same
pH	pH	Same
Potassium	Potassium	Same
Oxygen Saturation	Oxygen Saturation	Same
Hematocrit	Hematocrit	Same
Hemoglobin	Hemoglobin	Same
Shunt Temperature	Temperature	Same
Blood Flowrate	**Not included in predicate device**	New Functionality through added hardware
Calculated from existing data		
Oxygen Delivery Indexed Oxygen Delivery	Oxygen Delivery Indexed Oxygen Delivery	Same
Oxygen Consumption Indexed Oxygen Consumption	Oxygen Consumption Indexed Oxygen Consumption	Same
Oxygen Extraction Ratio	**Not included in predicate device**	New calculation using measured parameter data
Base Excess	Base Excess	Same
Bicarbonate	Bicarbonate	Same
Cardiac Index	**Not included in predicate device**	New calculation using measured parameter data
Oxygen Saturation	Oxygen saturation	Same
Acquired data		
Blood Flowrate (Entry or from HLM)	Blood Flowrate (Entry or from HLM)	Same
Body Surface Area (Entry)	Body Surface Area (Entry)	Same
Cerebral regional oxygen saturation (from Cerebral Oximetry Device)	**Not included in predicate device**	Connectivity to display information from alternate device

Table 2: Comparison of Technological Characteristics between the CDI OneView Monitoring System *(Subject Device) and the CDI 550 (Predicate Device)*

The only new measured characteristic added to the subject device that is not included in the predicate device is a flowrate sensor. The addition of flow rate does not add any additional issues of safety and effectiveness, as the previous capability to enter or acquire flowrate is now by direct measurement, known to be more accurate and timelier, and available to the clinician in multiple locations on the extra-corporeal circuit. Internal risk analysis conducted by Terumo Cardiovascular has shown that the clinical use of the flow meter adds no additional risk to the system and generates no new sources of patient harm. Directly measured blood flow rate does not change the risk profile of the device compared to the blood flow rate of the predicate device, as flow rate measurements have substantially similar hazardous situations resulting in equivalent harms. The flow rate measurement data is utilized by the clinician for the same purpose as other measurement parameters (namely optimizing treatment), utilizes the same interface, within the same sequences of events.

VIII. Performance Data

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Evaluation for electrical safety and EMC testing was conducted on the CDI OneView Monitoring System. The CDI OneView Monitoring System complies with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing was completed successfully. The fulfillment documentation is 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 CDI OneView Monitoring System is considered a "moderate" level of concern since a malfunction or latent design flaw of the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Design Verification and Validation Testing

Design verification testing was conducted and demonstrates that the CDI OneView Monitoring System performs pursuant to the defined design input requirements for the subject device. Design validation, including simulated use testing, was conducted and demonstrates that the CDI OneView Monitoring System meets the defined design input requirements for the subject device.

Animal Study

Animal testing was not required to demonstrate the substantial equivalence of the CDI OneView Monitoring System to the predicate device and is not included as part of this premarket notification.

Clinical Studies

Clinical testing was not required to demonstrate the substantial equivalence of the CDI OneView Monitoring System to the predicate device and is not included as part of this premarket notification.

IX. Conclusion

The information provided above supports that the CDI OneView™ Monitoring System is substantially equivalent to the predicate device with respect to the intended use and technological characteristics. Verification and validation testing supports that the hardware and software difference do not raise any new issues of safety and effectiveness. Therefore, it is concluded that the CDI OneView™ Monitoring System is substantially equivalent to the predicate device.