November 2, 2018

Terumo Cardiovascular Systems Corporation
Bryan Hann
Senior Engineer- Regulatory Affairs
6200 Jackson Road
Ann Arbor, Michigan 48103

Re: K182110
Trade/Device Name: CDI Blood Parameter Monitoring System 550
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary Bypass On-Line Blood Gas Monitor
Regulatory Class: Class II
Product Code: DRY
Dated: August 3, 2018
Received: August 6, 2018

Dear Bryan Hann:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2018.11.02 14:27:53 -04'00'

for 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182110

Device Name
CDI® Blood Parameter Monitoring System 550

Indications for Use *(Describe)*
The CDI System 550 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, oxygen delivery and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the systems integral printer provides a hard copy of displayed parameters.

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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Department of Health and Human Services
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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® Blood Parameter Monitoring System 550
510(k) Summary
This section is prepared in accordance with 21 CFR Part 807.92

General Information

Submitter's Name and Address	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor MI, 48103
Name of Contact Person	Bryan K. Hann
Phone number	Tel: (734) 741-5816
Fax number	Fax: (734) 741-6069
email	bryan.hann@terumomedical.com
Establishment Registration #	1828100
Date prepared	3 August 2018

Device Information

Trade Name	CDI® Blood Parameter Monitoring System 550
Common/Genric Name	Extracorporeal blood-gas monitor
Classification name	Monitor, Blood-gas, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Device Class	Class II
Regulation Number	21 CFR §870.4330
Product Code(s)	DRY

Predicate Device Information

The CDI Blood Parameter Monitoring System 550 is substantially equivalent in function and intended use to the CDI Blood Parameter Monitoring System 500 cleared in Premarket Notification K133658.

Indications for Use and Device Description

Indications for Use

The CDI System 550 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, oxygen delivery and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the systems integral printer provides a hard copy of displayed parameters.

Device Description

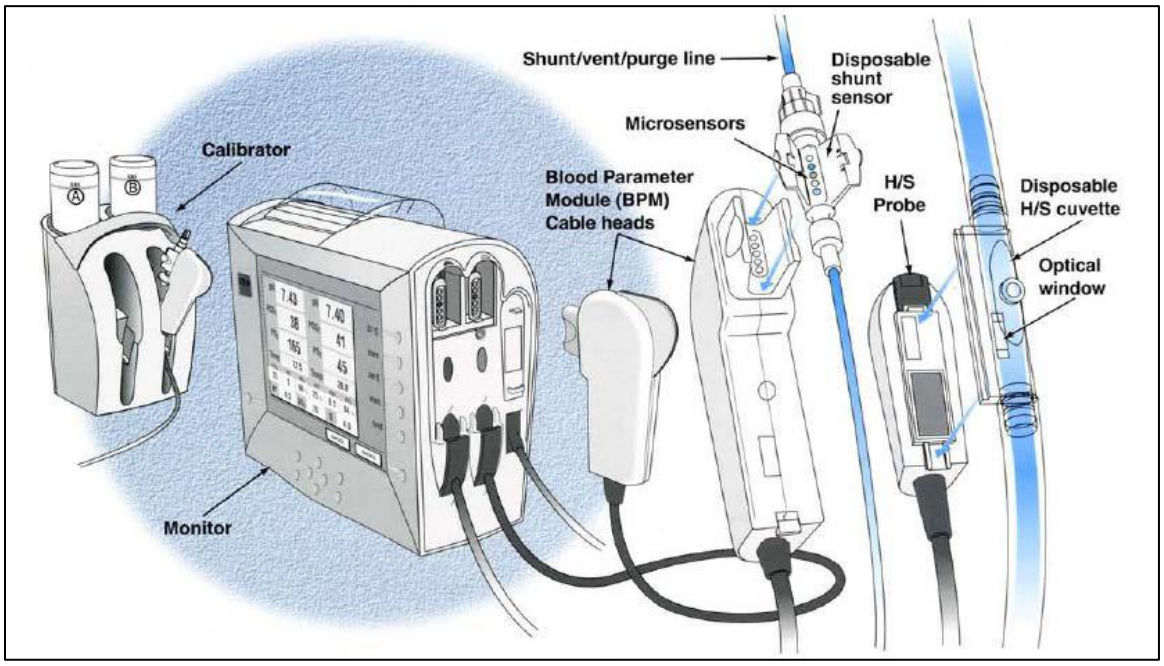
The CDI System 550 is an AC-powered (battery back-up) microprocessor-based device used with the following components/accessories:

- CDI 550 Monitor
- Arterial and/or Venous Blood Parameter Modules (BPM)
- CDI Hematocrit/Saturation (H/S) Probe
- CDI 540 Gas Calibrator and Calibration Gases (A and B)
- CDI 510H Shunt Sensor
- Shunt Bypass Line
- CDI H/S Cuvette with or without extension tubing
- Monitor Mounting Hardware (Pole Clamp and Cable Head Bracket)
- Printer Paper

The CDI System 550 measures blood parameters in real time by utilizing a microprocessor based monitor, electro-optics modules (i.e., BPM and H/S probe), fluorescence chemistry technology, and optical reflectance technology. The electro-optics modules connect the monitor to the disposables (i.e., shunt sensor or cuvette) which are inserted into the extracorporeal circuit. Light is emitted from the modules, and the optical responses from the blood via the sensor(s) are measured by the monitor. The blood parameters are measured or calculated by the CDI 550 Monitor in real time, and displayed to the user via a graphical LED display.

Section 4: 510(k) Summary

Device Illustration



Comparison of Technological Characteristics to Predicate Device

The CDI System 550 uses a microprocessor based monitor, electro-optics modules, fluorescence chemistry technology, and optical reflectance technology for measuring blood parameters in real time. The technology between the subject and predicate devices is equivalent and provides the basis for the following system functions:

- Blood parameters are measured or calculated by the monitor in real time and displayed to users via a graphical LED display.
- Monitors and displays the following blood parameters:

  Measured using the BPM

  - Partial pressure of oxygen (PO_2)
  - Partial pressure of carbon dioxide (PCO_2)
  - pH
  - Potassium (K+)
  - Temperature

  Calculated from the above BPM measured values

  - Bicarbonate (HCO_3)
  - Base Excess (BE)
  - Oxygen saturation (SO_2) (if the measured value is not available from the H/S Probe)

  Measured using the H/S Probe

  - Oxygen saturation (SO_2)
  - Hematocrit (Hct)
  - Hemoglobin (Hgb)
- Blood flow rate, Q, is either entered manually or via a serial interface between the CDI Monitor and the heart-lung machine. Blood flow rate can be displayed and is used to calculate oxygen consumption (VO_2).

The following differences exist between the subject and predicate devices:

- A new calculated blood monitoring parameter, Oxygen Delivery (DO_2), was added allowing users to monitor patient DO_2 levels during cardiopulmonary bypass. The Indications for Use statement was also updated to reflect this new parameter.
- Modifications to the alarms scheme pursuant to IEC 60601-1-8 (Edition 2.1): Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- Expanded hematocrit (HCT) and hemoglobin (Hgb) operating ranges and their corresponding modified accuracy claims.

- Improved temperature correction algorithm which resulted in modified blood parameter module (BPM) accuracy claims.
- Improved performance prior to in vivo calibration as measured by the HSAT Module.

Performance Data

Biocompatibility Testing

The CDI System 550 Monitor and 540 Calibrator do not come into contact with the patient, and there have been no changes to the disposable accessories. Biocompatibility testing was not required to demonstrate the substantial equivalence of the CDI System 550 to the predicate device and is not included as part of this premarket notification.

Electrical Safety and Electromagnetic Compatibility (EMC)

Evaluation for electrical safety and EMC testing was conducted on the CDI System 550. The CDI System 550 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 fullfillment 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 System 550 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 System 550 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 System 550 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 System 550 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 System 550 to the predicate device and is not included as part of this premarket notification.

Conclusion

The technological characteristics and fundamental scientific technology of the subject device have not changed from the predicate device. Software, design verification, and design validation testing have confirmed that the modifications do not adversely impact system performance. The CDI System 550 is substantially equivalent to the currently marketed CDI System 500 cleared under K133658.