Section 4: 510(k) Summary

This section includes a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Terumo Cardiovascular Systems Corporation
Address	6200 Jackson Road Ann Arbor MI, 48103
Name of Contact Person	Kevin Kong, RAC
Phone number	Tel: (734) 663-4145
Fax number	Fax: (734) 741-6069
E-mail	Kevin.Kong@terumomedical.com
Establishment Registration #	1828100
Date prepared	September 21, 2012
Name of Device	
Trade or proprietary name	CDI™ Blood Parameter Monitoring System 500
Common or usual name	Extracorporeal blood gas monitor
Classification name	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4330
Product Code(s)	DRY
Legally marketed device(s) to which equivalence is claimed	3M CDI Blood Parameter Monitoring System 500, K972962
Reason for 510(k)	Modification to previously cleared system

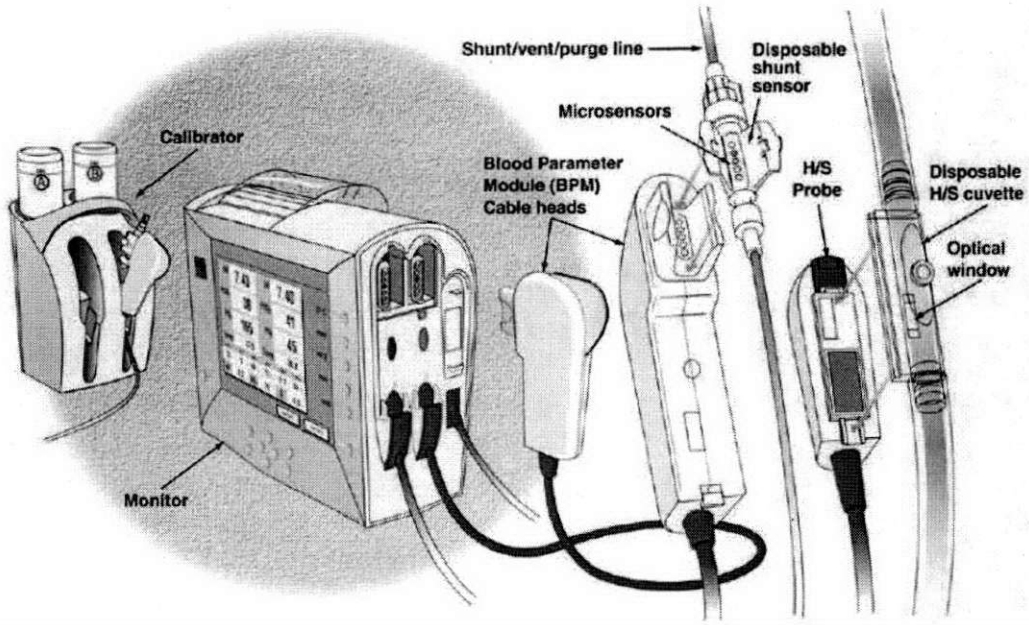
K123039

Section 4: 510(k) Summary

Device Information
Indication for Use: The CDI System 500 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, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.
Device Description: The CDI™ System 500 is an AC-powered (battery back-up) microprocessor-based device used with the following components/accessories: • CDI™ 500 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 500 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™ 500 Monitor in real time, and displayed to the user via a graphical LCD display.

K123039

Device Illustration:



Substantial Equivalence

The modified CDI™ System 500 is substantially equivalent to the original CDI™ System 500 cleared under K972962 because it has the same intended use and indications for use, same operating principles, and same performance specifications. The new and predicate devices are both used to continuously monitor blood parameters during procedures requiring extracorporeal circulation, monitoring the same blood parameters using the same operating principles. The CDI™ System 500 has been modified to improve the robustness of the Blood Parameter Module (BPM) probe cable-head against moisture ingress.

Below please find a side-by-side comparison of the modified to the original CDI™ System 500.

Item	New Device: Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device: 3M CDI Blood Parameter Monitoring System 500, K972962
Indication for Use	The CDI System 500 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, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.	The CDI System 500 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, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

K123039

Item	New Device: Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device: 3M CDI Blood Parameter Monitoring System 500, K972962
Blood Parameters Monitored (measured or calculated)	Arterial and/or Venous: pH pCO_2 (partial pressure of carbon dioxide) pO_2 (partial pressure of oxygen) K+ (potassium) SO_2 (oxygen saturation) Hct (hematocrit) Hgb (hemoglobin) Temperature BE (base excess) HCO_3 (bicarbonate) VO_2 (oxygen consumption) Blood flow rate (Q)	Arterial and/or Venous: pH pCO_2 (partial pressure of carbon dioxide) pO_2 (partial pressure of oxygen) K+ (potassium) SO_2 (oxygen saturation) Hct (hematocrit) Hgb (hemoglobin) Temperature BE (base excess) HCO_3 (bicarbonate) VO_2 (oxygen consumption) Blood flow rate (Q)
System Components	Monitor/control unit with integral printer Blood parameter module (BPM) probe - optionally one or two for arterial and/or venous use H/S probe Gas calibrator Gas A / Gas B canisters Disposable accessories (see below)	Monitor/control unit with integral printer Blood parameter module (BPM) probe - optionally one or two for arterial and/or venous use H/S probe Gas calibrator Gas A / Gas B canisters Disposable accessories (see below)

K123029

Item	New Device: Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device: 3M CDI Blood Parameter Monitoring System 500, K972962
Disposable Accessories	CDI510H Shunt Sensor (for arterial and venous use) with heparin coating Shunt Bypass Line ¼", 3/8", and ½" sizes 18" male/female extension line H/S Cuvettes, with or without 6" extension tube (cuvettes with heparin coating no longer available) ¼", 3/8", and ½" sizes	CDI510H Shunt Sensor (for arterial and venous use) with heparin coating In-line Sensor and In-line Cell ¼", 3/8", and ½" sizes H/S Cuvettes, with or without 6" extension tube, with or without heparin coating ¼", 3/8", and ½" sizes

K123039

K123039

Verification Testing on Device Modification

This 510(k) was submitted for a design change intended to improve the robustness of the CDI 500 Blood Parameter Module (BPM) Probe Cable-Head against moisture ingress. This design change did not alter the device indication for use or performance specifications.

Design control activities identified the requirements for the design change, which drove the design change verification activities. The design change was verified to meet pre-defined acceptance criteria and assure that:

- The BPM Probe Cable-Head functions as expected even in the presence of high humidity (85% RH)
- The design change does not introduce new safety risks
- The design change is effective over the expected life of the BPM probe cable-head

Conclusion
The modified CDI™ System 500 is substantially equivalent to the 3M CDI™ System 500 cleared under K972962 because it has the same intended use and substantially equivalent performance specifications as compared to these predicate devices.

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

Terumo Cardiovascular Systems Corp.
c/o Kevin Kong
Regulatory Affairs Specialist
6200 Jackson Road
Ann Harbor, MI 48103

NOV 2 0 2012

Re: K123039
Trade/Device Name: CDI Blood Parameter Monitoring System 500
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: DRY
Dated: September 21, 2011
Received: September 28, 2012

Dear Mr. Kong:

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.

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 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Indication for Use

510(k) Number: ~~TBD~~ K123039

Device Name: CDI™ Blood Parameter Monitoring System 500

Indications for Use:

The CDI System 500 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, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

Prescription Use X AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 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 K123039