April 18, 2023

Terumo Cardiovascular Systems Corporation
Eileen Dorsey
Sr. Manager, Regulatory Affairs
6200 Jackson Road
Ann Arbor, Michigan 48103

Re: K221895
Trade/Device Name: Terumo Advanced Perfusion System 1
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart-Lung Machine Console
Regulatory Class: Class II
Product Code: DTQ
Dated: March 10, 2023
Received: March 13, 2023

Dear Eileen Dorsey:

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/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 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 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,

Kathleen M. Grunder -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Terumo® Advanced Perfusion System 1

Indications for Use *(Describe)*

The Terumo® Advanced Perfusion System 1 is indicated for use for up to six hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

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.

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510(k) Summary

I. Submitter

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, MI 48103

Contact Person: Eileen Dorsey, Sr. Manager, Regulatory Affairs
Phone: 734-741-6074
Date Prepared: July 26, 2022

II. Device

Device Proprietary Name:	Terumo® Advanced Perfusion System 1
Common or Usual Name:	Heart-Lung Machine
Classification Name:	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4220
Product Code:	DTQ
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to:

- Advanced Perfusion System 1, K172220, Terumo Cardiovascular Systems Corporation

IV. Device Description

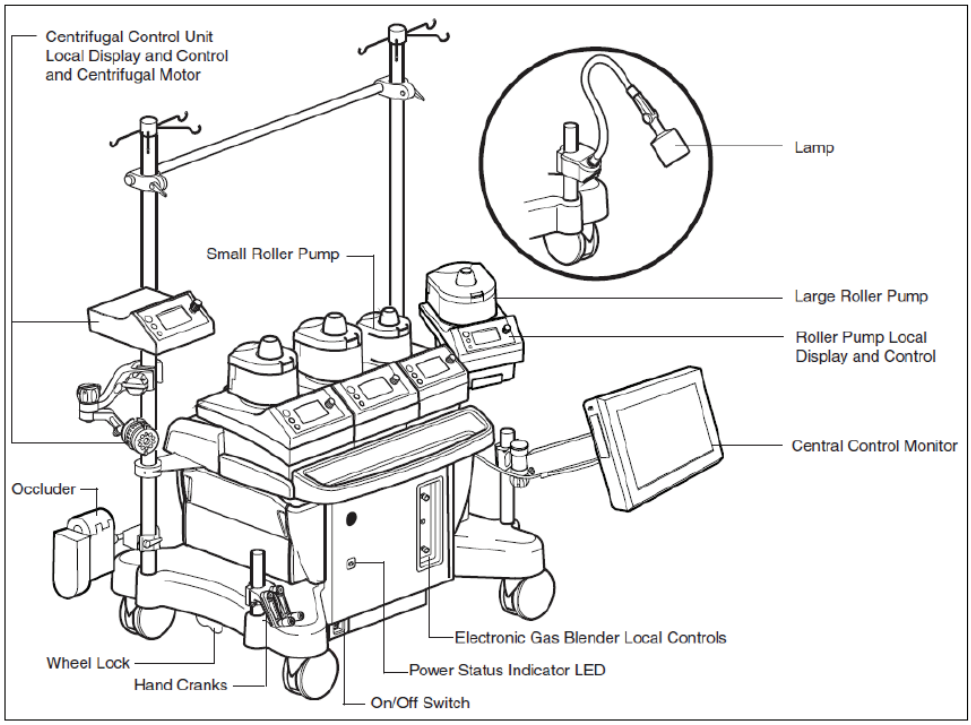
The Terumo® Advanced Perfusion System 1 (System 1) is a configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. The system is designed to enable users to choose from the Terumo CVS supplied components to define and configure a heart-lung system to meet individual institution requirements.

The System 1 components are listed below.

- System 1 Base:
    - Chassis platform - Provides operating power and back up battery power for all system components (100/120V or 220/240V)
    - Central Control Monitor (CCM) – A display used for configuration and control of system components
    - Two roller pump hand cranks and hand crank bracket

- Pump(s) and pump mounting hardware – Up to eight pumps can be used with System 1, including the following:
  - 6" Roller Pump
  - 4" Roller Pump
  - Centrifugal Control Unit with Centrifugal Drive Motor (up to 2)
- Pods
  - Air Bubble Detection Pod - Used to detect air bubbles in the extracorporeal circuit, in conjunction with the air sensor
  - Level Detection Pod - Used to monitor liquid levels within a hard shell reservoir.
  - Pressure Pod – Used to monitor the pressure in the extracorporeal circuit
  - Temperature Pod – Used to monitor the temperature in the extracorporeal circuit and / or the patient
  - Flowmeter Pod – Used to monitor flow volume and generate an alarm if backflow is detected
  - Venous Line Occluder Pod - Used with the Occluder Head to provide a computer controlled tube clamping mechanism to regulate flow in the venous line
  - Interface Pods to enable data transfer between cardiac monitoring and data display systems (i.e., Terumo CDI™ 500 Monitor, and TLink™ Data Management System)
- Electronic Patient Gas System (EPGS) - Provides control and monitoring of the gas output to the oxygenator
- Flexible Lamps (15 inch or 33 inch) for local illumination
- Mounting hardware (e.g., center poles, crossbars, and brackets)

Device Illustration



V. Indications for Use

The Terumo® Advanced Perfusion System 1 is indicated for use for up to six hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

VI. Comparison of Technological Characteristics

The indications for use for the subject and predicate devices are identical.

The subject and predicate devices are identical with respect to mechanism of action and all components except the Central Control Monitor (CCM). The CCM hardware (e.g., computer, PCB, storage, and supporting subassemblies) and associated software is being revised to address sub-assembly component obsolescence.

Key hardware modifications include replacing the CCM computer and touch screen with a flat-panel computer system. The flat-panel PC is electromechanically simpler than the current computer and touch screen as it has fewer components and fewer internal hardware interconnects. The subject CCM will support USB flash drives for external storage in place of PCMCIA flash memory cards. The CCM mounting arm was modified to accommodate the lighter CCM weight.

The following software modifications are being introduced:

- CCM Software updates for supporting the new CCM and USB LAN I/F hardware, QNX version upgrade to 6.5 and to provide support for USB flash drive storage.

- Software for USB LAN I/F for CAN-USB communications between the base and CCM, and real-time clock time keeping.

- Software for Power Manager Board to remove diagnostic battery current measurement test made unnecessary by new flat-panel PC

- Other minor software modifications:
    - Update system shut down counter to count down from 10 to 1 instead of up from 1 to 10
    - Correct On, Off and Mute buttons state display in Air subtab under specific circumstances
    - Update handling of system time change to prevent the display of a negative value while a perfusion timer is running

- Update pumps icon rotation speed graphics display for better consistency with actual pump speed
- Handle any onscreen keyboard display in case of fatal system shut down.
- Remove unnecessary error event logging in System event log
- Update dropdown list of temperature probe location labels

These changes do not raise different questions of safety or effectiveness as there is no impact to the intended use, indication for use, or operating principle.

VII. Performance Data

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

- Software validation
  Software system testing was conducted though testing performed following the Terumo Quality system. Software system testing relies on system level testing of the CCMD, LAN I/F , and Power Manager Pod as well as other Non-SST verification methods such as code reviews, integration testing, or other verification methods.

  Requirements are verified by software system testing and/or non-SST verification. These instances include some boundary tests and generation of messages that are unable to be tested through software system testing alone due to equipment constraints. The overall functionality of the requirement is verified through software system testing however other Non-SST test methods are required to fully verify the requirement.

  At the conclusion of Software validation, all requirements identified as software system requirements were successfully met.

- Hardware verification
  Hardware verification was conducted using testing, inspection, demonstration, and analysis techniques in accordance with TCVS procedures. The following activities were completed to show all design verification requirements were successfully met:

  - Internal testing: Internal testing was conducted under approved protocols to verify requirements were met for:
    - mounting arm performance,
    - mounting arm environmental conditions,
    - CCMD gloved hand response, and
    - power consumption.
  - External testing: External testing was performed to Standards:
    - Electrical safety testing per IEC 60601-1
    - Electromagnetic Compatibility testing per IEC 60601-1-2

    - Shipping and vibration testing per ISTA-3A and MIL-STD-810G, Method 514.6 (10Hz-100Hz)
  - Inspection: Inspections were conducted to verify requirements related to physical characteristics such as hardware characteristics and documentation.
  - Demonstration: System level demonstration was used to verify action-oriented features to test basic operations and deterministic behaviors of the design.
  - Analysis: Analyses were conducted to augment testing and other verification activities. This includes mounting arm and CCMD performance, CCMD environmental conditions, and power consumption.

- Reliability
  Verification of all requirements identified as device reliability requirements was conducted through testing, analysis, and similarity. These activities confirmed all applicable materials requiring cleaning and label adhesion successfully passed established acceptance criteria and that the CCMD meets all reliability targets and 12 year life.

- Validation
  Hardware validation was executed through testing under an approved protocol. Usability testers consisting of external perfusionists executed the use cases. This validation testing successfully completed verification of the requirements, user needs and risk mitigations within the project scope.

VIII. Conclusion

The information provided above supports that the Terumo® Advanced Perfusion System 1 is equivalent to the predicate device with respect to intended use and technological characteristics. Verification and validation testing supports that the hardware and software differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Terumo® Advanced Perfusion System 1 is substantially equivalent to the predicate device.