DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 27, 2015

Terumo Cardiovascular Systems Corporation
John Chesney
Senior Manager Regulatory Affairs
6200 Jackson Road
Ann Arbor, Michigan 48103

Re: K151349
Trade/Device Name: 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: July 17, 2015
Received: July 20, 2015

Dear Mr. Chesney,

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. 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); 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

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

Enclosure

Indications for Use

510(k) Number: K151349

Device Name: Advanced Perfusion System 1

Indications for Use:

The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 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.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use_____** (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)

K151349 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	John Chesney
Phone number	Tel: (734) 741-6410
Fax number	Fax: (734) 741-6069
email	John.Chesney@terumomedical.com
Establishment Registration #	1828100
Date prepared	May 18, 2015
Name of Device	
Trade or proprietary name	Terumo® Advanced Perfusion System 1
Common or usual name	Heart-Lung Machine
Classification name	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4220
Product Code(s)	DTQ
Legally marketed device(s) to which equivalence is claimed	Advanced Perfusion System 1: K131041
Reason for 510(k)	Software modifications to previously cleared system

510(k) Summary

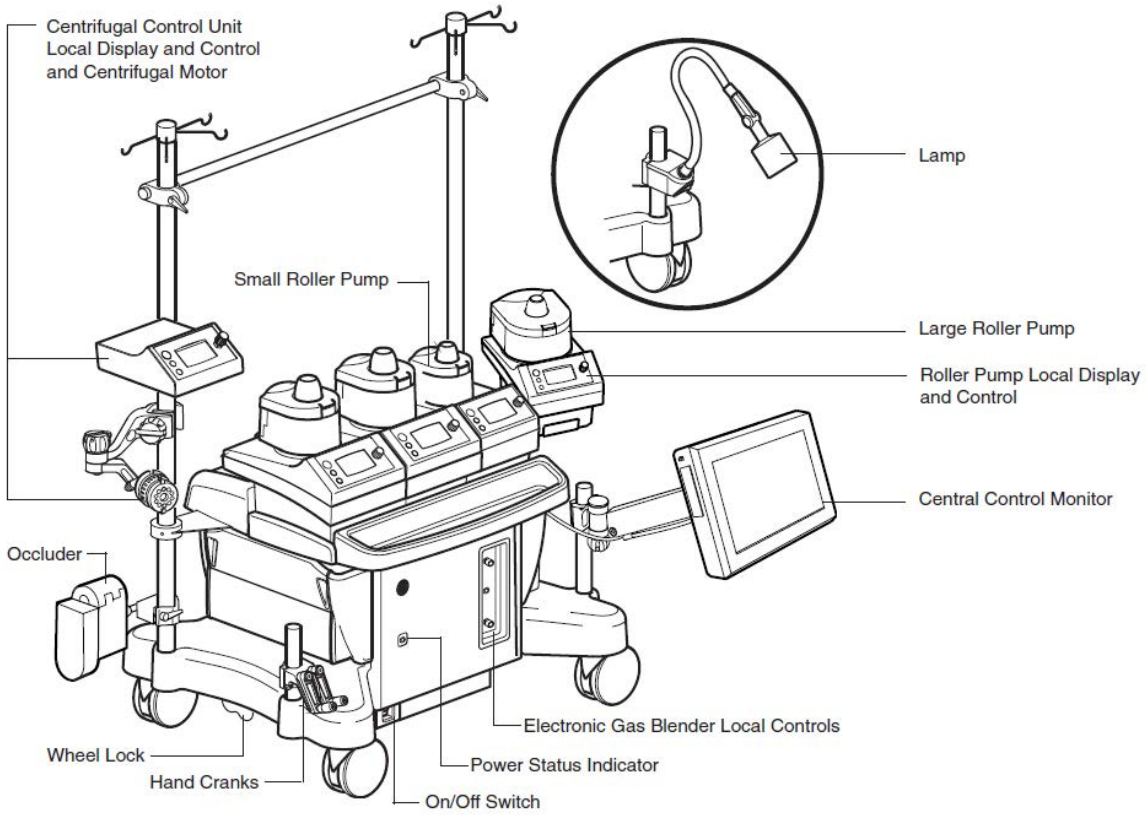
Device Information
Indication for Use: The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment. The centrifugal pump is indicated for use in cardiopulmonary bypass procedures only.

Device Description: The 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:
  o Chassis platform - Provides operating power and back up battery power for all system components (100/120V or 220/240V)
  o Central Control Monitor (CCM) – A touch screen display used for configuration and control of system components
  o 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:
  o 6” Roller Pump
  o 4” Roller Pump
  o Centrifugal Control Unit with Centrifugal Drive Motor (up to 2)
• Pods
  o Air Bubble Detection Pod - Used to detect air bubbles in the extracorporeal circuit, in conjunction with the air sensor
  o Level Detection Pod - Used to monitor liquid levels within a hard shell reservoir.
  o Pressure Pod – Used to monitor the pressure in the extracorporeal circuit
  o Temperature Pod – Used to monitor the temperature in the extracorporeal circuit and / or the patient
  o 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 (e.g., Terumo CDI™ 100 Monitor, CDI™ 500 Monitor, and TLink™ Data Management System)

- Electronic Gas Blender - 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:



Substantial Equivalence

The device software has been revised to improve system performance. There have been no changes that adversely impact system functions or operating principles. The Operator's Manual has been revised to clarify verbiage and revise some instructions for use. The modified System 1 is identical to the currently cleared System 1 because it has the same intended use, indications for use, and substantially equivalent operating principles and technical specifications.

Item	Proposed Device Modified System 1	Predicate Device System 1 (K131041)
Indication for Use	Identical to predicate device.	The Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 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.

System Components	Identical to predicate device.	• System 1 Base with CCM and various hardware accessories
		• Large (6") and/or Small (4") Roller Pumps
		• Centrifugal Control Unit and centrifugal drive motor
		• Optional pods and accessories, including:
		  o Air bubble detector
		  o Level sensor

Item	Proposed Device Modified System 1	Predicate Device System 1 (K131041)
		Optional o Pressure monitor o Temperature monitor o Flow monitor o Occluder o Electronic Gas Blender o Interface pods for external cardiac and data monitoring systems o Halogen lamps
Principles of Operation	Identical to predicate device.	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. Each component connects to the system network via points on the Base. There are six pump connections, two connections for the CCM, eighteen connections for pods and two dedicated connections for a lamp.
Power Supply	Identical to predicate device.	The power system within the Base transforms AC power into the DC levels required by the system components. Integrated batteries provide backup power in the event of AC power loss during use and when power needed exceeds power available.

Performance Testing

The software modifications implemented under this 510(k) were subjected to software verification and validation testing at the unit, integration, system, and regression levels.

Conclusion
The software modifications to the System 1 have not changed the device indications for use or fundamental scientific technology. Software verification and validation has confirmed that the modifications improve system performance. Therefore, the modified device is substantially equivalent to the currently marketed device cleared under K131041.