



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

December 16, 2015

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

Re: K153376

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: November 20, 2015  
Received: November 23, 2015

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. 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 (if known)

1 K153376

Device Name

Advanced Perfusion System 1

Indications for Use (Describe)

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.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"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."*

Terumo Cardiovascular Systems Corp.      Advanced Perfusion System 1 Special 510(k)

**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.

<b>Submitter Information</b>	
<b>Name</b>	Terumo Cardiovascular Systems Corporation
<b>Address</b>	6200 Jackson Road Ann Arbor MI, 48103
<b>Name of Contact Person</b>	Bryan Hann
<b>Phone number</b>	Tel: (734) 741-5816
<b>Fax number</b>	Fax: (734) 741-6069
<b>email</b>	bryan.hann@terumomedical.com
<b>Establishment Registration #</b>	1828100
<b>Date prepared</b>	November 20, 2015
<b>Name of Device</b>	
<b>Trade or proprietary name</b>	Terumo® Advanced Perfusion System 1
<b>Common or usual name</b>	Heart-Lung Machine
<b>Classification name</b>	Console, Heart-Lung Machine, Cardiopulmonary Bypass
<b>Classification panel</b>	74 Cardiovascular
<b>Regulation</b>	21 CFR §870.4220
<b>Product Code(s)</b>	DTQ
<b>Legally marketed device(s) to which equivalence is claimed</b>	Advanced Perfusion System 1: K151349
<b>Reason for 510(k)</b>	Hardware modification to previously cleared system

**Section 4: 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.

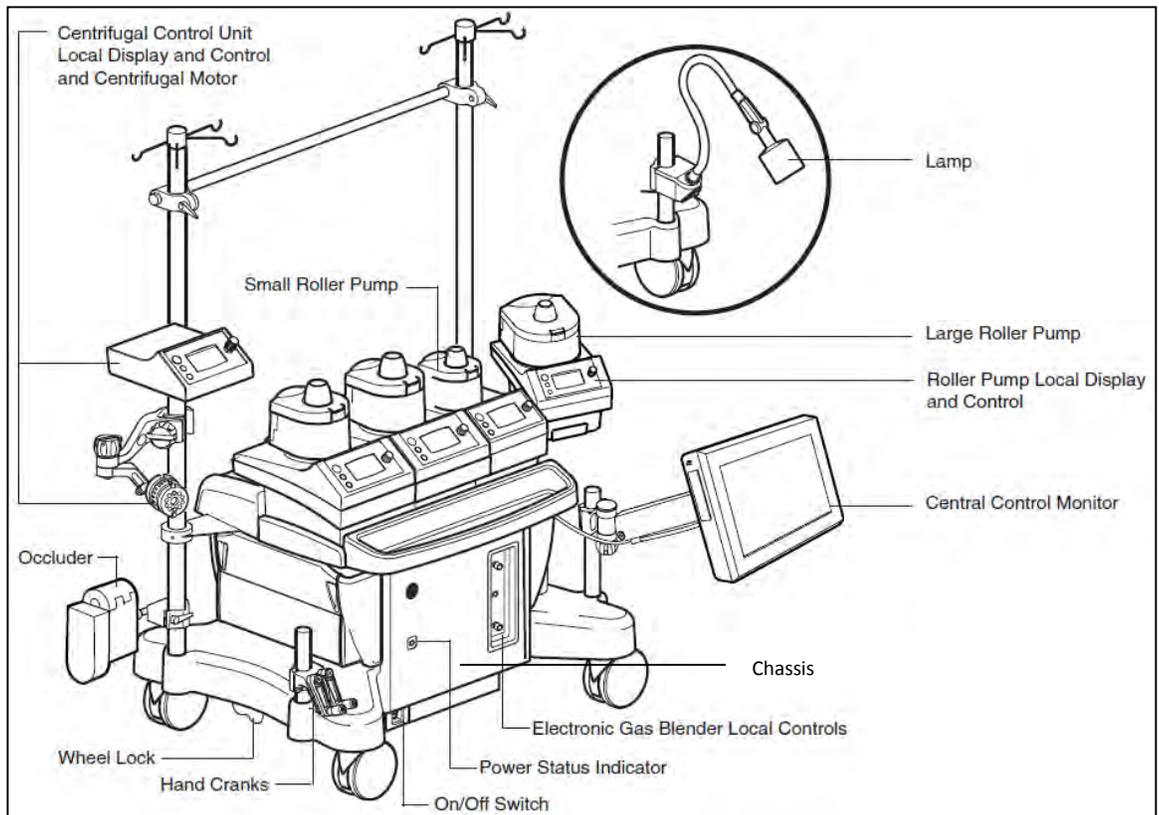
**Device Description:** The Advanced Perfusion System 1 (System 1) is a configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. The 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:
  - Chassis platform - Provides operating power and back up battery power for all system components (100/120V or 220/240V)
  - Central Control Monitor (CCM) – A touch screen 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

**Section 4: 510(k) Summary**

- 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:**

**Section 4: 510(k) Summary**

---

**Device Function:** The System 1 relies on either roller pumps or a centrifugal pump combined with roller pumps to circulate fluids during extracorporeal circulation. Roller pumps rely on a pair of revolving rollers that occlude the tubing of the extracorporeal circuit against a stationary tubing guide in such a way that the fluid in the short segment of tubing between the rollers is propelled within the tubing in the direction of the rollers rotation.

Pumps are typically employed for an arterial (main physiological support) circuit, delivery of cardioplegia solution directly to the heart, suction and venting. According to user preference, a centrifugal pump may be used in place of a roller pump for the arterial circuit. The centrifugal pump is a non-occlusive impeller that propels the fluid within the tubing within the circuit in the direction of the rotation of the impeller blades.

**Section 4: 510(k) Summary**

**Substantial Equivalence**

The System 1 hardware has been modified to prevent inadvertent shut off and / or failure of the On/Off Switch which could result in a loss of system power. The proposed modification does not adversely impact the system functions or operating principles. The Operator’s Manual has been revised to include a previous customer communication on what to do in the event of a loss of sytem power. The subject System 1 has the same indications for use, intended use, as well as substantially equivalent operating principles and technological charateristics as the predicate device.

Item	Subject Device	Predicate Device (K151349)
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.	<ul style="list-style-type: none"> <li>• System 1 Base with CCM and various hardware accessories</li> <li>• Large (6”) and/or Small (4”) Roller Pumps</li> <li>• Centrifugal Control Unit Local Display and Control and Centrifugal Motor</li> <li>• Optional pods and accessories, including:                             <ul style="list-style-type: none"> <li>○ Air bubble detector</li> <li>○ Level sensor</li> </ul> </li> </ul>

**Section 4: 510(k) Summary**

---

Item	Subject Device	Predicate Device (K151349)
		Optional <ul style="list-style-type: none"> <li>○ Pressure monitor</li> <li>○ Temperature monitor</li> <li>○ Flow monitor</li> <li>○ Occluder</li> <li>○ Electronic Gas Blender</li> <li>○ Interface pods for external cardiac and data monitoring systems</li> <li>○ Lamps</li> </ul>

**Section 4: 510(k) Summary**

Item	Subject Device	Predicate Device (K151349)
Principles of Operation	Identical to predicate device.	<p>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.</p> <p>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.</p>
Chassis	Identical to predicate device with exception of a new On/Off switch, switch guard, and ancillary installation hardware.	The power system within the Chassis 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.
Operator's Manual	Identical to the predicate device with the exception of a instruction on what to do in the event of loss of system power	The labeling supplied with the device is intended to provided users of the System 1 with proper operating instructions.

**Section 4: 510(k) Summary**

---

**Performance Testing**

The hardware modification implemented under this Special 510(k) was subjected to successful design verification and validation testing.

<b>Conclusion</b>
<p>The labeling and hardware modification to the System 1 has not changed the device indications for use or fundamental scientific technology. Hardware verification and validation testing has confirmed that the modification satisfies the design input requirements and prevents inadvertent loss of system power. The modified device is substantially equivalent to the current predicated device cleared under K151349.</p>