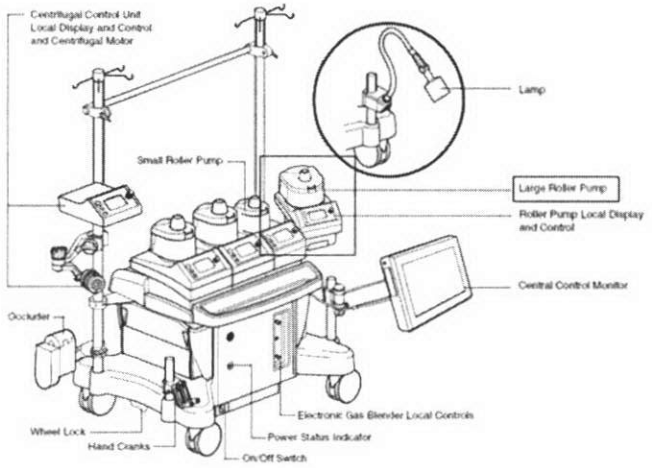
K131618

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	John Chesney
Phone number	Tel: (734) 741-6410 SEP 27 2013
Fax number	Fax: (734) 741-6069
E-mail	john.chesney@terumomedical.com
Establishment Registration #	1828100
Date prepared	September 27, 2013
Name of Device	
Trade or proprietary name	Large (6") Roller Pump for Terumo® Advanced Perfusion System 1
Common or usual name	Cardiopulmonary bypass roller pump
Classification name	Pump, blood, cardiopulmonary bypass, roller type
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4370
Product Code(s)	DWB
Legally marketed device(s) to which equivalence is claimed	Large (6") Roller Pump for Terumo® Advanced Perfusion System 1, K112587
Reason for 510(k)	Modifications to previously cleared system

Device Information
Device Description: The Large (6") Roller Pump of the Advanced Perfusion System 1 (System 1) is a peristaltic pump with a 6 inch diameter race. It can be mounted on the base of the System 1 console or can be positioned in an optimal location in the perfusion circuit by mounting on the pole. Pump operation can be configured using the System 1 Central Control Monitor (CCM). A local user interface display and control panel is also located on the front of the pump. The large roller pump can accommodate applications requiring flow rates up to 10 L/min including adult and pediatric arterial, cardioplegia, vent and suction pumping. The pump has a variable tube clamp mechanism that accommodates a variety of tubing sizes, including dual tube sets.
Indication for Use: The Large (6") Roller Pump for the 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.
Device Illustrations



Section 4: 510(k) Summary

Substantial Equivalence

The modified Large (6") Roller Pump for the System 1 is substantially equivalent to the currently cleared Large (6") Roller Pump for the System 1 because it has the same intended use, substantially equivalent indications for use, and the same or substantially equivalent operating principles and technical specifications. The device software has been revised to improve system performance; however, there have been no changes to system functions or operating principles.

Item	**Proposed Device** **Modified Large (6") Roller Pump for the System 1**	**Predicate Device** **Large (6") Roller Pump for the System 1 – K112587**
Indication for Use	The large (6") roller pump for 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 large (6") roller pump for 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.
Functional Summary	Large roller pump with 6" race can accommodate applications requiring flow rates up to 10 L/min including adult and pediatric arterial, cardioplegia, vent and suction pumping	Large roller pump with 6" race can accommodate applications requiring flow rates up to 10 L/min including adult and pediatric arterial, cardioplegia, vent and suction pumping
Tubing Requirements	Commercially available tubing meeting the following specifications: • Medical Grade PVC	Commercially available tubing meeting the following specifications: • Medical Grade PVC tubing

Section 4: 510(k) Summary

Item	**Proposed Device** **Modified Large (6") Roller Pump for the System 1**	**Predicate Device** **Large (6") Roller Pump for the System 1 – K112587**
	• 11/16" OD (max) • 1/16" – 3/32" wall thickness	• 11/16" OD (max) • 1/16" – 3/32" wall thickness
Panel Displays and Controls	Front panel for user interface controls, functional displays, and alarm conditions	Front panel for user interface controls, functional displays, and alarm conditions
Pump Configurations / Modes	Pump can be configured using the System 1 Central Control Monitor (CCM) as: • Arterial pump • Cardioplegia pump Arterial pump can be run in Continuous, Pulse, Servo, or Master/Follower mode.	Pump can be configured using the System 1 Central Control Monitor (CCM) as: • Arterial pump • Cardioplegia pump Arterial pump can be run in Continuous, Pulse, Servo, or Master/Follower mode.
Internal Monitoring, Controls and Safety Features	Pump continuously monitors its own performance and reports status information and problems to the user via the pump display panel alarms and to the CCM. Pump responses to detected problems can include Stop, Pause, Reduce Speed, or Message Only.	Pump continuously monitors its own performance and reports status information and problems to the user via the pump display panel alarms and to the CCM. Pump responses to detected problems can include Stop, Pause, Reduce Speed, or Message Only.
Mounting	Pump can be mounted on System 1 base or pole. The attachment mechanism is integral to the back of the lower pump housing.	Pump can be mounted on System 1 base or pole. The attachment mechanism is integral to the back of the lower pump housing.

Section 4: 510(k) Summary

Item	**Proposed Device** **Modified Large (6") Roller Pump for the System 1**	**Predicate Device** **Large (6") Roller Pump for the System 1 – K112587**
Dimensions (nominal)	Height: 12.5 in (31.8 cm) Width: 8.5 in (21.6 cm) Depth: 13.1 in (33.3 cm)	Height: 12.5 in (31.8 cm) Width: 8.5 in (21.6 cm) Depth: 13.1 in (33.3 cm)
Weight (nominal)	26 lb (11.7 kg)	26 lb (11.7 kg)
Housing	External: Molded ABS plastic. Internal: Metal with EMC coating	External: Molded ABS plastic. Internal: Metal with EMC coating
Cover	Clear plastic cover with safety interlock	Clear plastic cover with safety interlock
Pump Control Assembly	A two-board assembly, consisting of a computer board and a motor control board are mounted to the frame.	A two-board assembly, consisting of a computer board and a motor control board are mounted to the frame.
Power	Low voltage, 24 VDC power and battery backup supplied from APS1 via the pump power cable.	Low voltage, 24 VDC power and battery backup supplied from APS1 via the pump power cable.
Flow Range Accuracy	• 0.001 L/min for 0.0 – 1.0 L/min ± 10% of actual • 0.01 L/min for 1.0 – 10.0 L/min ± 8% of actual	• 0.001 L/min for 0.0 – 1.0 L/min ± 10% of actual • 0.01 L/min for 1.0 – 10.0 L/min ± 8% of actual

Section 4: 510(k) Summary

Item	**Proposed Device** **Modified Large (6") Roller Pump for the System 1**	**Predicate Device** **Large (6") Roller Pump for the System 1 – K112587**
Speed Range / Accuracy	0 – 250 RPM ± 2 RPM or 1% of actual, whichever is greater	0 – 250 RPM ± 2 RPM or 1% of actual, whichever is greater
Environmental Conditions (Operation)	• 10°C to 40°C • ≤ 75%RH • Non-condensing	• 10°C to 40°C • ≤ 75%RH • Non-condensing
Environmental Conditions (Storage)	• Store in ventilated area • -30°C to 54°C • ≤ 95%RH • Non-condensing	• Store in ventilated area • -30°C to 54°C • ≤ 95%RH • Non-condensing
Electrical Rating	• 24 VDC (nominal) • +5 VDC • 10A maximum @ 24 VDC	• 24 VDC (nominal) • +5 VDC • 10A maximum @ 24 VDC

Performance Testing

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

Conclusion
The software modifications to the Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1 have not changed the device indications for use or fundamental scientific technology. Software and system testing have confirmed that the modifications improve device performance. Therefore, the modified device is substantially equivalent to the currently marketed device cleared under K112587.

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

September 27, 2013

Terumo Cardiovascular Systems Corporation
Mr. John Chesney
Sr. Manager Regulatory Affairs
6200 Jackson Rd.
Ann Arbor, MI 48103

Re: K131618
Trade/Device Name: Large (6") Roller Pump for Terumo Advanced Perfusion System 1
Regulation Number: 21 CFR 870.4370
Regulation Name: Cardiopulmonary Bypass Roller Pump
Regulatory Class: Class II
Product Code: DWB
Dated: August 14, 2013
Received: August 15, 2013

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 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. 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 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 -S

Bram D. Zuckerman, Ph.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: K131618

Device Name: **Large (6") Roller Pump for Terumo® Advanced Perfusion System 1**

Indications for Use:

The Large (6") Roller Pump for 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.

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)

Bram D. Zuckerman -S
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