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

November 17, 2016

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

Re: K162843
Trade/Device Name: Small (4") Roller Pump for the Terumo Advanced Perfusion System 1, Large (6") Roller Pump for the Terumo Advanced Perfusion System 1
Regulation Number: 21 CFR 870.4370
Regulation Name: Roller-Type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class II
Product Code: DWB
Dated: October 7, 2016
Received: October 11, 2016

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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162843

Device Name
Small (4") and Large (6") Roller Pumps for the Terumo® Advanced Perfusion System 1.

Indications for Use *(Describe)*

The Small (4") and Large (6") Roller Pumps for the Terumo® Advanced Perfusion System 1 are 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.

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.

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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	Bryan Hann
Phone number	Tel: (734) 741-5816
Fax number	Fax: (734) 741-6069
email	bryan.hann@terumomedical.com
Establishment Registration #	1828100
Date prepared	October 7, 2016
Name of Device	
Trade or proprietary name	Small (4”) Roller Pump for the Terumo® Advanced Perfusion System 1
	Large (6”) Roller Pump for the Terumo® Advanced Perfusion System 1
Common or usual name	Cardiopulmonary bypass roller pump
Classification name	Roller–type cardiopulmonary bypass blood pump
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4370
Product Code(s)	DWB
Legally marketed device(s) to which equivalence is claimed	Terumo® Advanced Perfusion System 1: K153376

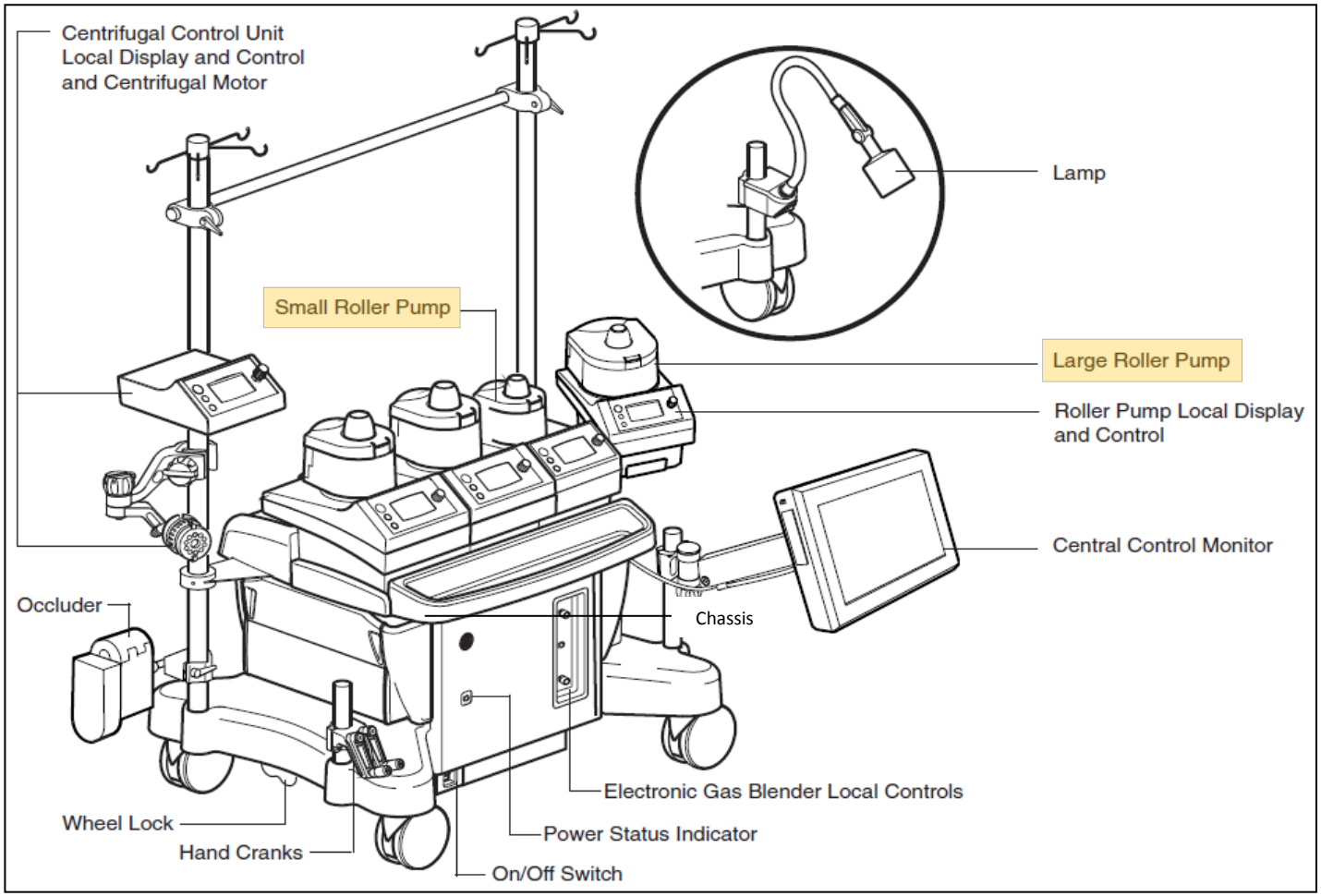
Section 4: 510(k) Summary

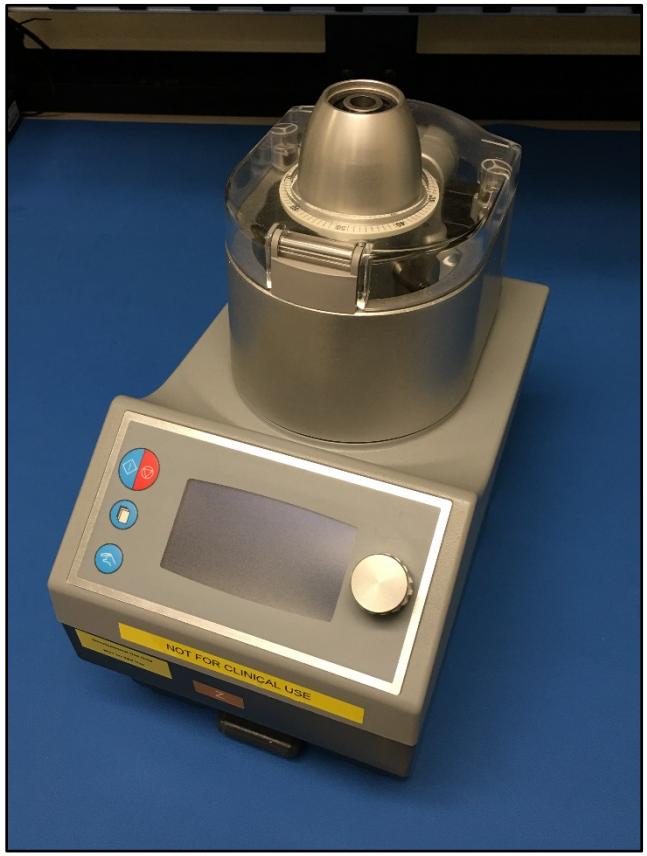
Reason for 510(k)	Update to the System 1 Operator's Manual (instructions for use) that incorporates the use of medical grade silicone tubing with the Small (4") and Large (6") System 1 Roller Pumps.

Section 4: 510(k) Summary

Device Information
Indication for Use: The Small (4”) and Large (6”) Roller Pumps of the Terumo® Advanced Perfusion System 1 are 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 Description: The Small (4”) and Large (6”) Roller Pumps of the Terumo® Advanced Perfusion System 1 (System 1) are peristalic pumps with 4 inch and 6 inch diameter raceways. The pumps 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 to the system poles. Operation of the pumps can be configured using the System 1 Central Control Monitor (CCM). Local user interface displays and control panels are also located on the front of the large and small roller pumps. The small roller pump can accommodate applications requiring flow rates up to 4 L/min including pediatric arterial, adult and pediatric cardioplegia, vent and suction pumping, whereas 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 small and large roller pumps both have variable tube clamp mechanisms that accommodate a variety of tubing sizes, including dual tube sets.

Device Illustration:



Small (4”) and Large (6”) Roller Pumps of the Terumo® Advanced Perfusion System 1	
Small (4”) Roller Pump	**Large (6”) Roller Pump**
	

Section 4: 510(k) Summary

Device Function: The Small (4”) or Large (6”) System 1 Roller Pumps are designed 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.

Substantial Equivalence

The Small (4”) and Large (6”) Roller Pumps for the System 1 have been qualified for use with medical grade silicone tubing through performance testing. The use of medical grade silicone tubing does not adversely impact the system functions or operating principles. The Operator’s Manual has been revised to include the use of medical grade silicone tubing. The subject Small (4”) and Large (6”) Roller Pumps for the System 1 have the same indications for use, intended use, as well as substantially equivalent operating principles and technological charateristics as the predicate device.

Item	**Subject Devices** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**
Indication for Use	Identical to predicate device.	The Small (4”) and Large (6”) Roller Pumps of the Terumo® Advanced Perfusion System 1 are 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	Identical to predicate device.	Small roller pump can accommodate applications requiring flow rates up to 4 L/min including pediatric arterial, adult and pediatric cardioplegia, vent and suction pumping.
		Large roller pump can accommodate applications requiring flow rates up to 10 L/min including adult and pediatric arterial, cardioplegia, vent and suction pumping.

Item	Subject Devices Small (4") Roller Pump for the System 1 Large (6") Roller Pump for the System 1	Predicate Devices (K153376) Small (4") Roller Pump for the System 1 Large (6") Roller Pump for the System 1
Tubing Requirements	**Small Roller Pump** Commercially available tubing meeting the following specifications: • Medical Grade PVC o 9/16" Outer Diameter (max) o 1/16" – 3/32" wall thickness • Medical Grade Silicone o 9/16" outer diameter (max) o 1/16" – 3/32" wall thickness	**Small Roller Pump** Commercially available tubing meeting the following specifications: • Medical Grade PVC o 9/16" outer diameter (max) o 1/16" – 3/32" wall thickness
	Large Roller Pump Commercially available tubing meeting the following specifications: • Medical Grade PVC o 11/16" Outer Diameter (max) o 1/16" – 3/32" wall thickness • Medical Grade Silicone o 11/16" outer diameter (max) o 1/16 – 3/32" wall thickness	**Large Roller Pump** Commercially available tubing meeting the following specifications: • Medical Grade PVC o 11/16" outer diameter (max) o 1/16" – 3/32" wall thickness

Item	**Subject Devices** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**
Panel Displays and Controls	Identical to predicate device.	Front panels for user interface controls, functional displays, and alarm conditions.
Pump Configurations / Modes	Identical to predicate device.	**Small Roller Pump** Small roller pump can be configured using the System 1 Central Control Monitor (CCM) as: • Arterial pump (neonatal / pediatric only) • Cardioplegia pump • Vent pump • Suction pump Arterial pump can be run in Continuous, Pulse, Servo, or Master/Follower mode

Item	**Subject Devices** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**
	Identical to predicate device.	**<u>Large Roller Pump</u>** Large roller pump can be configured using the System 1 Central Control Monitor (CCM) as: • Arterial pump (adult and pediatric) • Cardioplegia pump • Vent pump • Suction pump Arterial pump can be run in Continuous, Pulse, Servo, or Master/Follower mode
Internal Monitoring, Controls and Safety	Identical to predicate device.	The small and large roller pumps both continuously monitors its own performance and reports status information and problems to the user via the pump display panel alarms and to the CCM. Responses to detected problems can include Stop, Pause, Reduce Speed, or Message Only.
Mounting	Identical to predicate device.	The small and large roller pumps can be mounted on the System 1 base or to the poles via mounting support brackets.

Item	**Subject Devices** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**
Dimensions	Identical to predicate device.	**Small Roller Pump** • Height: 12.5 in (31.8cm) • Width: 7.1 in (18.0 cm) • Depth: 13.1 (30.0 cm)
		Large Roller Pump • Height: 12.5 in (31.8cm) • Width: 8.5 in (21.6 cm) • Depth: 13.1 (33.3 cm)
Weight (nominal)	Identical to predicate device	**Small Roller Pump** • 23.5 lb (10.7 kg)
		Large Roller Pump • 28.5 lb (12.9 kg)
Housing	Identical to predicate device	External: Molded ABS plastic. Internal: Metal with EMC coating.
Cover / Pump Lid	Identical to predicate device	Clear plastic with safety interlock.

Item	**Subject Devices** **Small (4") Roller Pump for the System 1** **Large (6") Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4") Roller Pump for the System 1** **Large (6") Roller Pump for the System 1**
Pump Control Assembly	Identical to predicate device.	A two board assembly, consisting of a computer board and a motor control board that are mounted to the frame.
Power	Identical to predicate device.	Low voltage, 24 VDC power and battery backup supplied from APS1 via pump power cables.
Flow Range Accuracy	Identical to predicate device.	**Small Roller Pump** • 0.001 L/min for 0.0 – 1.0 L/min ± 10% of actual • 0.01 L/min for 1.0 – 4.0 L/min ± 8% of actual **Large Roller Pump** • 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
Speed Range / Accuracy	Identical to predicate device.	0 – 250 RPM ± 2 RPM or 1% of actual.

Item	**Subject Devices** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**	**Predicate Devices (K153376)** **Small (4”) Roller Pump for the System 1** **Large (6”) Roller Pump for the System 1**
Environmental Conditions (Operations)	Identical to predicate device.	• 10°C to 40°C • ≤ 75% Relative Humidity • Non-condensing
Environmental Conditions (Storage)	Identical to predicate device.	• Stored in ventilated area • -30°C to 54°C • ≤ 95% Relative Humidity • Non-condensing
Electrical Rating	Identical to predicate device.	• 24 VDC (nominal) • +5 VDC • 7.4 A maximum @ 24 VDC

Performance Testing

Performance testing of medical grade silicone tubing with the Small and Large System 1 Roller Pumps has been completed successfully.

Conclusion
The use of medical grade silicone tubing with the Small and Large System 1 Roller Pumps has not changed the device indications for use or fundamental scientific technology. Performance testing has confirmed that the design input requirements were met demonstrating that medical grade silicone tubing can be used with the Small and Large System 1 Roller Pumps. The device is substantially equivalent to the current predicated device cleared under K153376.