



August 17, 2017

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

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

Re: K172220

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, KFM, DWB
Dated: July 19, 2017
Received: July 24, 2017

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,


Nicole G. Ibrahim -S

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)

K172220

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.

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Section 4: 510(k) Summary

Terumo® Advanced Perfusion System 1
510(k) Summary

This section is prepared in accordance with 21 CFR Part 807.92

General Information

Submitter's Name and Address	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor MI, 48103
Name of Contact Person	Bryan K. Hann
Phone number	Tel: (734) 741-5816
Fax number	Fax: (734) 741-6069
email	bryan.hann@terumomedical.com
Establishment Registration #	1828100
Date prepared	19 July 2017

Device Information

Trade Name	Terumo® Advanced Perfusion System 1
Common/Generic Name	Heart-Lung Machine
Classification name	Console, Heart-Lung Machine, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Device Class	Class II
Regulation Number	21 CFR §870.4220
Product Code(s)	DTQ

Predicate Device Information

The modified Terumo® Advanced Perfusion System 1 is substantially equivalent in function and intended use to the Terumo® Advanced Perfusion System 1 cleared in Premarket Notification K163531.

Section 4: 510(k) Summary

Indications for Use and Device Description**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.

Device Description

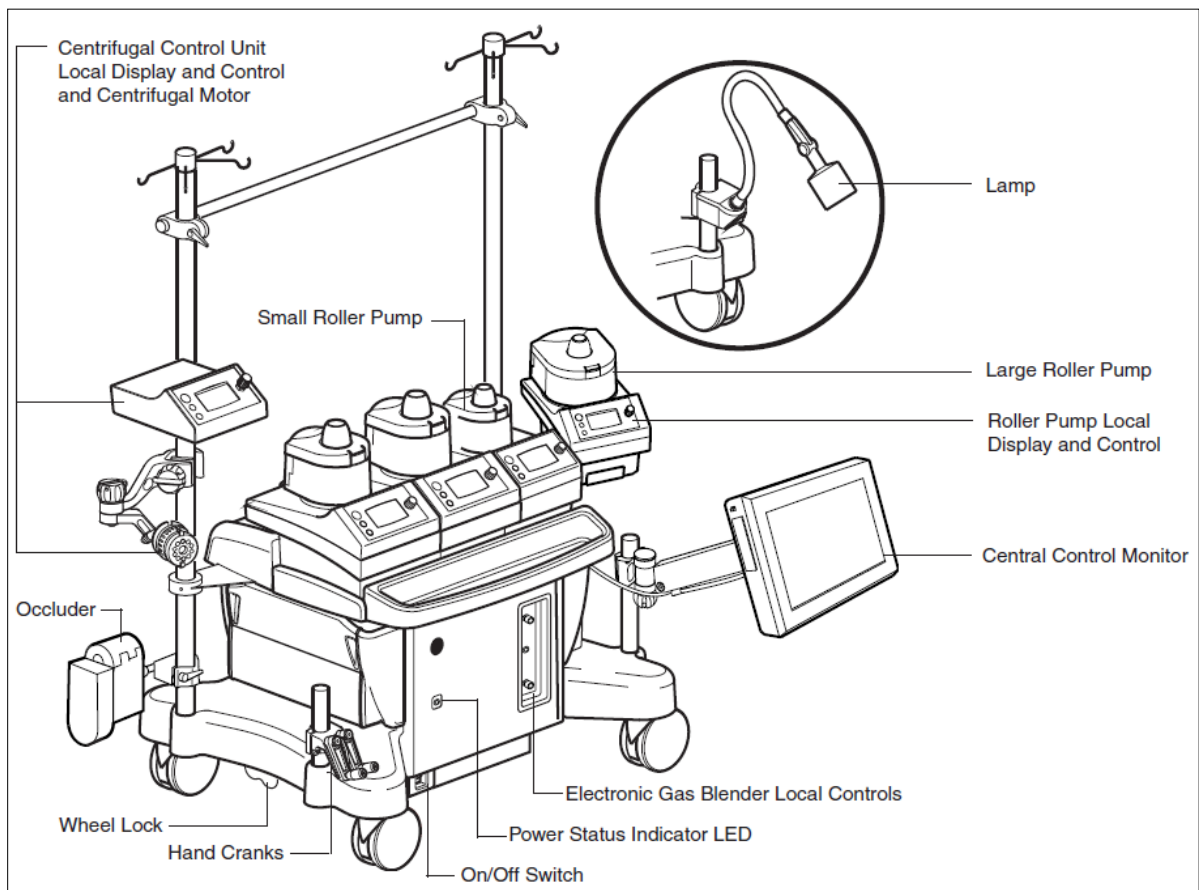
The Advanced Perfusion System 1 (System 1) is a configurable heart-lung system with a distributed network architecture that allows the user to customize the number and types of system components, which can then be configured, displayed, and controlled from a central monitor. The system is designed to 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 (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

Comparison of Technological Characteristics to Predicate Device

Extracorporeal circulation of blood is the technological principle for both the subject and predicate System 1 devices. This is based on the use of centrifugal pumps as well as roller pumps for the circulation of blood in arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures. The subject and predicate devices are based on the following technological principles:

- CCM used for configuration and control of system components
- Centrifugal and roller type pumps used for extracorporeal circulation of blood
- The use of pods to connect peripheral components and devices for safety, monitoring, and data transfer
- EPGS for control and monitoring of the gas output to the oxygenator

The following technological differences exist between the subject and predicate devices:

- The O₂ analyzer calibration routine has been modified to calibrate at two gas flow rates instead of one.
- The addition of notifications to the CCM to inform users of the EPGS calibration status.

Performance Data

Biocompatibility Testing

The Terumo® System 1 does not come into contact with the patient. Therefore biocompatibility testing is not included as part of this premarket notification.

Electrical Safety and Electromagnetic Compatibility (EMC)

This premarket notification is limited to the software modifications to the EPGS and the CCM of the System 1. These software modifications do not impact Electrical Safety and Electromagnetic Compatibility of the product, therefore testing was not conducted.

Software Verification and Validation Testing

Software verification and validation testing were conducted and discussion of the these activities (i.e. protocols, acceptance criteria, and test results) at the unit, integration, and system level are included as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Design Verification and Validation Testing

Design verification testing was not required as software verification and validation testing has addressed the design input requirements and software requirement specifications.

Design validation testing was conducted and demonstrates that the System 1 performs within the defined design input requirements for the proposed modifications. The following testing was performed on the subject device:

- Simulated use case testing
- Validation of the Instructions For Use changes

Animal Study

Animal testing was not required to demonstrate the substantial equivalence of the System 1 to the predicate device and is not included as part of this premarket notification.

Clinical Studies

Clinical testing was not required to demonstrate the substantial equivalence of the System 1 to the predicate device and is not included as part of this premarket notification.

Conclusion

The software modifications to the System 1 have not changed the device indications for use, technical characteristics, or fundamental scientific technology. Software verification and validation, and design validation testing have confirmed that the modifications do not adversely impact system performance. The modified System 1 is substantially equivalent to the currently marketed device cleared under K163531.