February 9, 2021

Terumo Medical Corporation
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Saint Paul, Minnesota 55114

Re: K112382
Trade/Device Name: Terumo Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Mark Job:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 14, 2011. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.02.09 08:16:35 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Terumo Medical Corporation
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

DEC 14 2011

Re: K112382/S1
Trade/Device Name: Terumo Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 14, 2011
Received: November 15, 2011

Dear Mr. Job:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 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): K112382

Device Name: Terumo Aspiration Catheter

Indications For Use:

The Terumo Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

M.A. Villalobos

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112382

510(k) Summary

A. *Device Name*

Proprietary Name	Terumo Aspiration Catheter
Classification Name	Embolectomy Catheter (as per 870.5150)
Common Name	Embolectomy Catheter, Aspiration Catheter
Product Code	DXE

B. *Intended Use*

The Terumo Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

The predicate devices are the PRONTO V3 Extraction Catheter (K083784) and the Medtronic Export XT Catheter (K061958).

The PRONTO V3 Extraction Catheter (K083784) is indicated for removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

The Medtronic Export XT Catheter (K061958) is indicated for:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To subselectively infuse/deliver diagnostics or therapeutic agents with or without vessel occlusion.

The Terumo Aspiration Catheter has the same indication for use as the Pronto V3 predicate device. Unlike the Export XT device, the Terumo Aspiration Catheter is not indicated for the infusion or delivery of diagnostic or therapeutic agents. This difference does not alter the safety or effectiveness of the Terumo Aspiration Catheter when used as indicated.

C. *Device Description*

The Terumo Aspiration Catheter is a dual lumen rapid exchange catheter. The guidewire lumen is used to facilitate passage of a guide wire which must not exceed 0.014" (0.36 mm) in diameter. The larger extraction lumen allows the removal of thrombus (thrombi) by use of the included aspiration syringe through the extension line. The catheter has a proximal stiff region and a distal flexible region that is coated with hydrophilic polymer which generates lubricity when wet. On the distal tip a

radiopaque marker band is incorporated. The proximal end of the catheter is equipped with a standard luer adapter to facilitate the attachment of the included extension line, stopcock and syringes. The provided stylet can be inserted in the catheter to assist in the delivery of the catheter to the vascular lesion. The included flushing tool is used to flush the guide wire lumen in preparation for use. A filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis or any thrombosis.

D. Principle of Operation / Technology

The Terumo Aspiration Catheter is operated manually or by manual process. This is the same principle of operation of the predicate devices.

E. Design / Materials

The Terumo Aspiration Catheter submitted in this 510(k), the PRONTO V3 extraction catheter cleared under K083784 and the Medtronic Export XT Aspiration Catheter cleared under K061958 have the same principle design features:

- Dual lumen for rapid exchange over a guidewire
- Wire braided tubing for enforced strength
- Distal marker band for high visibility under fluoroscopy
- External hydrophilic coating for easy access to vascular lesion

All three devices have a three-layered construction comprising a stainless steel wire or mesh sandwiched in between an inner and outer elastomer layer.

	Pronto V3	Export XT	Terumo Aspiration Catheter
Outer Layer	Poly-ether-block-amide, Nylon 12	Poly-amide-elastomer	Polyamide Elastomer, Nylon 12
Braid	Stainless Steel	Stainless Steel	Stainless Steel
Inner Layer	Poly-olefin	Not disclosed	PFA (per-fluoroalkoxy) resin

The Terumo Aspiration Catheter in this submission uses similar types of materials as the predicate devices. The results of biological compatibility and bench testing show that the differences in materials between the Terumo Aspiration Catheter and the predicate devices do not raise any new issues of safety and effectiveness.

F. *Specifications*

The Terumo Aspiration Catheter submitted in this 510(k), the PRONTO V3 extraction catheter cleared under K083784 and the Medtronic Export XT Aspiration Catheter cleared under K061958 have similar device specifications. Differences in specifications between the devices do not raise any new issues of safety and effectiveness.

	Catheter Length	Maximum O.D.	Compatible Guiding Catheter size	Compatible Guidewire size	Extraction lumen area
Terumo Aspiration Catheter	140 cm	1.70 mm	6 Fr.	0.014"	0.85 mm^2
		1.90 mm	7 Fr.		1.28 mm^2
Pronto V3	140 cm	1.60 mm	6 Fr.	0.014"	0.93 mm^2
Export XT	140 cm	1.73 mm	6 Fr.	0.014"	0.85 mm^2
		1.83 mm	7 Fr.		1.27mm^2

G. *Performance*

1. Conformance to ISO 10555-1

The Terumo Aspiration Catheter successfully passed the following performance tests, demonstrating conformance with ISO 10555-1:

ISO 10555-1 Compliance Testing of the Terumo Aspiration Catheter (aged, sterile)		
Test	Test methods	Result
Surface inspection	ISO 10555-1	Passed
Corrosion resistance	ISO 10555-1	Passed
Force at break (shaft, hub)	ISO 10555-1	Passed
Freedom from leakage	ISO 10555-1	Passed

The above tests were conducted using both real-time aged and accelerated aged samples.

A minimal force at break of 4N was applied to distal marker and distal tip bonding (based on ISO10555-3). This is more stringent than 3N requirement of 10555-1. No other deviations or exclusions were taken from methods defined in ISO 10555-1.

2. Potential changes over shelf life

To evaluate the potential for performance changes over the stated shelf life, the following additional bench testing was conducted using non-aged (t=0) samples:

- Catheter force at break
- Catheter lubricity
- Dimensional verification
- Stylet coil bond tensile strength
- Stylet to connector tensile strength
- Extension line tensile strength:

All non-aged samples met all specifications and no significant changes in performance were observed between the t=0 and the t=shelf life samples.

3. Comparison to predicates

The following in-house bench testing was conducted to demonstrate equivalent performance with the predicate devices.

In-House Comparative Performance Testing	
Test	Method
Kink resistance	Dimensional measurement (distance and radius) of kinked, fixed-length sample of catheter shaft.
Aspiration rate	Measurement of time required to aspirate known volume of viscous fluid.
Thrombus aspiration capability	Gram weight measurement of aspirated simulated clot.
Pushability	Measurement of resistance encountered traversing a guiding catheter
Trackability	Measurement of resistance and distance travelled through anatomical (PCTA) model

Performance characteristics of the Terumo Aspiration Catheter were found to be equivalent or superior to the predicate devices.

4. Accessories

Components/accessories were also tested as indicated in the following table. Each component successfully passed all required tests. No exclusions or deviations were taken for any of the applied standards. All testing was conducted using both real-time aged and accelerated aged samples.

Conformance Testing of Accessory Components (aged, sterile)		
Component	Test Methods	Result
Stylet	ISO 10555-1	Passed
Stylet connector	ISO 594-1 & 2	Passed
Aspiration syringe	ISO 7886-1	Passed
Aspiration syringe luer	ISO 594-1 & 2	Passed
Extension Line	ISO 10555-1	Passed
Extension Line luers and stopcock	ISO 594-1 & 2	Passed
Flushing tool	ISO 594-1 & 2	Passed

H. Biocompatibility and Sterilization

The Terumo Aspiration Catheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24h). Blood contacting materials were tested in accordance with FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". No deviations or exclusions were taken from the methods defined in the applicable parts of ISO 10993. The Terumo Aspiration Catheter successfully passed all of the following biocompatibility tests:

Biocompatibility Testing of the Terumo Aspiration Catheter (non-aged, sterile)		
Test	Test methods	Result
Sensitization	ISO 10993-10	Meets the requirements
Hemolysis	ASTM F756	Non-hemolytic
Dog thrombo-resistance	ISO 10993-4	Non-thrombogenic
Complement Activation	ISO 10993-4	Meets the requirements
Ames Assay	ISO 10993-3	Meets requirements
Lymphoma Forward Mutation	ISO 10993-3	Non-mutagenic
Bone Marrow Micronucleus	ISO 10993-3	Non-clastogenic
Rabbit Pyrogen	ISO 10993-11	Non-pyrogenic
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Intracutaneous reactivity	ISO 10993-10	Meets requirements
Acute Systemic toxicity	ISO 10993-11	Non-toxic

In addition, the following screening tests were conducted on the accelerated aged, sterile device to demonstrate that aging does not affect the device's biocompatibility:

Biocompatibility Testing on the Terumo Aspiration Catheter (aged, sterile)		
Test	Test methods	Result
Physicochemical profile	USP 661	Meets the requirements
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Hemolysis	ASTM F756	Non-hemolytic

Again, no deviations or exclusions were taken from the methods defined in the applicable standards.

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals will meet requirements for limited exposure devices (contact up to 24 hours) prior to use, based on ANSI/AAMI/ISO 10993-7, Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

The Terumo Aspiration Catheter is individually packaged in a peel package composed of polyester-polyethylene laminated film and Tyvek. Expiration dating for the Terumo Aspiration Catheter is 36-months based on performance testing in accordance with ISO 10555-1, of both real-time aged (>3years) and accelerated aged samples, and validation of package integrity in accordance with ISO11607-1 and ISO11607-2.

I. Substantial Equivalence

The Terumo Aspiration Catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, and materials to the Pronto V3 extraction catheter which was cleared under K083784 and the Medtronic Export XT Aspiration Catheter which was cleared under K061958. Differences between the devices do not raise any issues of safety or effectiveness.

J. Submitter Information

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