SECTION II. 510(K) SUMMARY

A. Device Name

Proprietary Name:	Terumo Support Catheter
Classification Name:	Percutaneous catheter
Common Name:	Percutaneous catheter

B. Intended Use

Terumo Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

C. Device Description

The Terumo Support Catheter is a three-layer construction comprised of a stainless steel braid sandwiched between two layers of polyester elastomer. The polyester elastomer contains tungsten for visibility and contrast under fluoroscopy in the distal portion of the catheter. The most distal tip contains no braid and the tip is available in either straight or curved shapes. The device has three radiopaque markers, the distal one is embedded in the tip wall while the more proximal two are swaged to the outer surface of the catheter. There is a hydrophilic coating on the distal portion of the catheter to enhance lubricity.

D. Principle Of Operation / Technology

The Terumo Support Catheter is operated manually or by a manual process.

During an interventional or diagnostic procedure, the physician will follow the standard procedure of placing a guide wire and introducer within a vessel. Then a guiding catheter or sheath would be advanced over the guide wire. Next, the Terumo Support Catheter would be inserted over the guide wire and through the hemostasis valve of the guiding catheter or sheath. The guide wire and Terumo Support Catheter would then be advanced to the target vessel. The Terumo Support Catheter can then be used for injection of contrast media or for support and exchange of guide wires.

E. Design / Materials

The Terumo Support Catheter in this submission uses similar materials as the predicate devices. Differences in materials between the devices do not raise any new issues of safety and effectiveness. Below is a table with a comparison of the materials used in the Terumo Support Catheter and the predicate devices:

		QUICK CROSS CATHETERS	QUICK CROSS EXTREME SUPPORT CATHETERS	Terumo Support Catheter
		K033678	K092396	—
Design	Construction	Single layer	Three layers	Three layers
	Number of Radiopaque markers	3	3	3
Material	Inner layer	Polyethlene	PTFE	Polyester elastomer
	Braid	-	Stainless steel	Stainless steel
	Outer layer	-	Polyamide elastomer	Polyester elastomer
	Radiopaque marker	Platinum	Platinum	Platinum alloy

F. Specifications

The Terumo Support Catheter submitted in this 510(k), the Spectranetics QUICK CROSS CATHETERS cleared under K033678 and the Spectranetics QUICK CROSS EXTREME SUPPORT CATHETERS cleared under K092396 have similar device specifications. Differences in specifications between the devices do not raise any new issues of safety and effectiveness.

Item	QUICK CROSS CATHETERS	QUICK CROSS EXTREME SUPPORT CATHETERS	Terumo Support Catheter
Effective lengths	65, 90, 135, 150 cm	65, 90, 135, 150 cm	65, 90, 135, 150 cm
Number of Radiopaque markers	3	3	3
Radiopaque marker spacing	15mm, 50mm	50mm	40mm, 60mm
Guidewire Compatibility	0.014, 0.018, 0.035 inch	0.035 inch	0.035 inch
Maximum Injection Pressure	300psi	500psi	750psi
Inner diameter	1.13mm	0.98mm	1.05mm
Outer diameter	1.60mm	1.50mm	1.39mm
French size	5Fr	5Fr	4Fr
Tip design/ shape	Straight	Angle	Straight/Angle

G. Performance

The Terumo Support Catheter submitted in this 510(k), and the Spectranetics QUICK CROSS CATHETERS cleared under K033678 and the Spectranetics QUICK CROSS EXTREME SUPPORT CATHETERS cleared under K092396 have similar performance characteristics. The following performance tests were conducted on these catheters. Testing was performed on nonaged and aged Terumo Support Catheters vs the Spectranetics QUICK CROSS CATHETERS and the Spectranetics QUICK CROSS EXTREME SUPPORT CATHETERS.

1) Force at break (shaft, hub, tip)
2) Freedom from leakage
3) Radio detectability
4) Catheter burst/leakage pressure
5) Breakage strength of catheter shaft
6) Bending stiffness of catheter shaft
7) Flexibility/Kink strength of catheter shaft
8) Torque transmission property
9) Interior sliding characteristics
10) Exterior sliding characteristics
11) Wire-support characteristics
12) Flow rate
13) Simulated use testing
14) Torque strength testing

The performance of the Terumo Support Catheter is substantially equivalent to the performance of the predicate devices.

In addition, the following tests were performed on the Terumo Support Catheter to assure proper performance:

1) Surface
2) Product dimension (ID, OD, effective length)
3) Fitting strength of strain relief to hub
4) Hub pull test
5) Tip pull test
6) Coating Integrity
7) Particulate Evaluation

The Terumo Support Catheter met all performance specifications.

H. Additional Safety Information

Blood contacting materials were tested in accordance with the tests recommended in the 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".

The catheter is classified as Externally Communicating Devices, Circulating Blood, limited Contact (<24 hrs). Results of the testing demonstrate that the blood contacting materials are biocompatible. The Terumo Support Catheter successfully passed all of the following biocompatibility tests:

Biocompatibility Test Reports - Non-aged Device:

- Cytotoxicity
- Maximization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemolysis
- Pyrogen test
- Thrombogenicity Study in Dogs
- Complement Activation Assay

Biocompatibility Test Reports - Aged Device:

- Physiochemical Profile
- Cytotoxicity
- Hemolysis

Sterilization conditions have been validated in accordance with ANSI/AAMI/ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10^{-6}.

I. Substantial Equivalence

The Terumo Support Catheter submitted in this 510(k) is substantially equivalent in the general intended use, design, technology/principles of operation, materials, and performance to the Spectranetics QUICK CROSS CATHETERS cleared under K033678 or the Spectranetics QUICK CROSS EXTREME SUPPORT CATHETERS cleared under K092396. Differences between the devices do not raise any new issues of safety or effectiveness.

J. Submitter Information

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Date Prepared: January 28, 2011

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

MAY 13 2011

Re: K110540
Trade/Device Name: Terumo Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 22, 2011
Received: April 25, 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,

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): K110540

Device Name: Terumo Support Catheter

Indications For Use:

Terumo Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110540