K002882

Section II: 510(k) Summary

FEB 2 6 2010

A. Device Name

Proprietary Name

TERUMO Surshield-PUR Safety I.V. Catheter

Classification Name

Intravascular Catheter (880.5200)

Panel & Product Code: 80FOZ

Classification: Class II

Common Name

Intravascular catheter with needle protection device

B. Predicate Device

The TERUMO Surshield-PUR Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent[1] with respect to intended use, safety mechanism, design, materials, manufacturing, sterilization, technology/principles of operation, and performance to the following:

Polyurethane catheter material

-K991406 TERUMO Surflash I.V. Catheter

AND

-K082997 TERUMO Hybria Closed System Safety I.V. Catheter

Ethylene Terafluoro Ethylene catheter material

-K082362 TERUMO Surshield Safety I.V. Catheter

AND

[1] A statement of substantially equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used a evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

-K090973 TERUMO Surshield Safety I.V. Catheter (51mm catheter length)

The differences between the devices do not raise any new issues of safety or effectiveness.

C. Intended Use

The TERUMO Surshield-PUR Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

D. Description

The TERUMO Surshield-PUR Safety I.V. Catheters are devices consisting of an over-the needle, peripheral catheter made of a slender, flexible, radio-opaque plastic with a hub that is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluids intravenously, or monitor blood pressure by attaching a monitoring line. The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system. The sharp end of the inner needle is covered by the steel guard as the needle is withdrawn from the catheter's hub to aid in the prevention of needle stick injuries. This is a passive safety mechanism.

E. Principle of Operation / Technology

The TERUMO Surshield-PUR Safety I.V. Catheter is operated manually.

F. Design / Materials

The design of the TERUMO Surshield-PUR Safety I.V. Catheter and the materials used to manufacture the TERUMO Surshield-PUR Safety I.V. Catheter are identical to the currently marketed TERUMO Surshield Safety I.V. Catheter (K082362 and K090973) except for the catheter portion. Polyurethane is the catheter material used in the manufacture of the currently marketed TERUMO Surflash I.V. Catheter (K991406) and TERUMO Hybria Closed System Safety I.V. Catheter (K082997). The catheter gauge,

length and diameter ranges are all within the range of the currently marketed predicate devices.

G. Specifications

Product code numbers and specifications are provided in **Table II-1.**

TABLE II-1: Device Specifications for TERUMO Surshield -PUR Safety I.V. Catheter

Product code	Catheter gauge	Color code	Catheter length	Catheter O.D*(I.D)	Flow rate	Lumen volume**
SR*SFF1832A	18G	Deep Green	1-1/4""(32mm)	1.3(0.95)mm	100mL/min	23μL
SR*SFF1851A	18G	Deep Green	2"(51mm)	1.3(0.95)mm	90mL/min	36μL
SR*SFF2025A	20G	Pink	1""(25mm)	1.1(0.80)mm	65mL/min	13μL
SR*SFF2032A	20G	Pink	1-1/4""(32mm)	1.1(0.80)mm	60mL/min	16μL
SR*SFF2051A	20G	Pink	2"(51mm)	1.1(0.80)mm	55mL/min	26μL
SR*SFF2225A	22G	Deep blue	1""(25mm)	0.9(0.60)mm	35mL/min	7μL
SR*SFF2232A	22G	Deep blue	1-1/4""(32mm)	0.9(0.60)mm	30mL/min	9μL
SR*SFF2419A	24G	Yellow	3/4"(19mm)	0.7(0.47)mm	15mL/min	3μL

*Catheter O.D. is labeled value. **Catheter only

H. Performance

Performance testing was conducted in accordance with the consensus standards and design control requirements. All performance testing conducted on the TERUMO Surshield-PUR Safety I.V. Catheter manufactured by Terumo Corporation determined that the modified device was substantially equivalent to the predicate devices.

I. Substantial Equivalence

The TERUMO Surshield-PUR Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent with respect to intended use, safety mechanism, design, materials, manufacturing, sterilization, technology/principles of operation, and performance to the following predicate devices:

Polyurethane catheter material

-K991406 TERUMO Surflash I.V. Catheter

AND

-K082997 TERUMO Hybria Closed System Safety I.V. Catheter

Ethylene Tetrafluoro Ethylene catheter material

-K082362 TERUMO Surshield Safety I.V. Catheter

AND

-K090973 TERUMO Surshield Safety I.V. Catheter (51mm catheter length)

The differences between the devices do not raise any new issues of safety or effectiveness.

J. Submitter Information

Date Prepared: 01/28/2010

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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

MAR 22 2010

Terumo Corporation
C/O Ms. Christina Flanagan
Regulatory Affairs Specialist
Terumo Medical Corporation
950 Elkton Boulevard
Elkton, Maryland 21921

Re: K100282
Trade/Device Name: TERUMO® Surshield® -PUR SAFETY I.V. CATHETER
Regulation Number: 21 1CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 28, 2010
Received: February 01, 2010

Dear Ms. Flanagan:

This letter corrects our substantially equivalent letter of February 26, 2010.

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 (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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthsiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: TERUMO® Surshield®-PUR SAFETY I.V. CATHETER

Indications For Use:

The TERUMO® Surshield®-PUR SAFETY I.V. CATHETER is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluids intravenously, or monitor blood pressure by attaching a monitoring line. The needle-shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100282