K133280

JUN 12 2014

510(k) SUMMARY

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared for : TERUMO (PHILIPPINES) CORPORATION
124 East Main Avenue, Laguna Technopark,
Binan, Laguna,Philippines

Prepared by : Ma. Cristina Faderagao – Supervisor, Regulatory Affairs
Tel. (+63) 49 541 2111
Fax (+63) 49 541 2121

Date prepared : September 26, 2013

Contact Person : Phillip Michael Lester
Regulatory Affairs Specialist
Terumo Medical Corporation
950 Elkton Boulevard
Elkton, MD 21921
Phone#: (410)392-7321
Fax#: (410)398-6079
E-mail: philmichael.lester@terumomedical.com

B. DEVICE NAME (807.92(a)(2))

Proprietary Name

TERUMO® SURFLO® I.V. Catheter or similar proprietary name

Classification Name

Intravascular Catheter (880.5200)

Product Code: FOZ

Panel: General Hospital

Classification: Class II

Common Name

Intravascular catheter

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is the TERUMO® SURFLO® I.V. Catheter (K891087), manufactured by Terumo Medical Corporation, Elkton, Maryland.

D. REASON FOR 510(K) SUBMISSION

This premarket notification (510(k)) is being submitted for the TERUMO® SURFLO® I.V. Catheter, an intravascular device, manufactured by Terumo (Philippines) Corporation, as a new device.

E. INTENDED USE (807.92(a)(5))

TERUMO® SURFLO® I.V. Catheter is inserted into the patient's vascular system for short term use (less than 30 days) to withdraw blood samples, monitor blood pressure, or administer fluids intravenously.

Note: This intended use is substantially equivalent to the predicate device, TERUMO® SURFLO® I.V. Catheter (K891087).

F. DEVICE DESCRIPTION (807.92(a)(4))

(Summary of Technological Characteristics)

Principle of Operation and Technology

The TERUMO® SURFLO® I.V. Catheter is manually operated.

Design/Construction

The SURFLO® I.V. Catheter is a device consisting of a catheter assembly (catheter, caulking pin, and catheter hub) and needle assembly (needle, needle hub, filter cap and filter).

The device is 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 (<30days) use to withdraw blood samples, administer fluids intravenously, or monitor blood pressure by attaching a monitoring line.

Material

The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system.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 needle assembly contains a plug and membrane filter which prevents blood leakage.

The catheter that is advanced into the vessel is made of ethylene tetrafluoro ethylene, which is the same as TERUMO® SURFLO® I.V. Catheter (K891087), manufactured by Terumo Medical Corporation, Elkton, Maryland.

Specifications

The TERUMO® SURFLO® I.V. Catheter will be individually packaged by case unit and sterilized by electron beam. It is available in 14, 16, 18, 20, 22 and 24 gauge catheters diameters and 19, 25, 32, 51, and 64 mm catheter lengths.

Product Code	Catheter Gauge	Color Code	Catheter length	Catheter OD (ID)	Flow rate	Lumen Volume*
SR-OX1464CA	14G	Orange	2 ½" (64mm)	2.15mm (1.73mm)	300 mL/min	120 µL
SR-OX1451CA	14G	Orange	2" (51mm)	2.15mm (1.73mm)	305 mL/min	120 µL
SR-OX1664CA	16G	Gray	2 ½" (64mm)	1.70mm (1.30mm)	180 mL/min	68 µL
SR-OX1651CA	16G	Gray	2" (51mm)	1.70mm (1.30mm)	190 mL/min	68 µL
SR-OX1632CA	16G	Gray	1 ¼" (32mm)	1.70mm (1.30mm)	200 mL/min	68 µL
SR-OX1864CA	18G	Green	2 ½" (64mm)	1.30mm (0.96mm)	85 mL/min	23 µL
SR-OX1851CA	18G	Green	2" (51mm)	1.30mm (0.96mm)	90 mL/min	23 µL
SR-OX1832CA	18G	Green	1 ¼" (32mm)	1.30mm (0.96mm)	100 mL/min	23 µL
SR-OX2051CA	20G	Pink	2" (51mm)	1.10mm (0.78mm)	55 mL/min	16 µL
SR-OX2032CA	20G	Pink	1 ¼" (32mm)	1.10mm (0.78mm)	60 mL/min	15 µL
SR-OX2025CA	20G	Pink	1" (25mm)	1.10mm (0.78mm)	65 mL/min	12 µL
SR-OX2225CA	22G	Blue	1" (25mm)	0.85mm (0.62mm)	35 mL/min	7 µL
SR-OX2419CA	24G	Yellow	3/4" (19mm)	0.67mm (0.47mm)	15 mL/min	3 µL

*Catheter only

G. NON CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the safety and effectiveness of the TERUMO® SURFLO® I.V. Catheter throughout the shelf life, verify conformity to the applicable part of ISO standards, and demonstrate substantial equivalence to the predicate device, as mentioned in the table below.

No new issues of safety and effectiveness were raised with the testing performed. Performance testing demonstrates that the TERUMO® SURFLO® I.V. Catheter conforms to the recognized consensus ISO standards, is substantially equivalent to the predicate devices, and acceptable for clinical use throughout the shelf life.

The following performance tests were performed on TERUMO® SURFLO® I.V. Catheter, manufactured by Terumo (Philippines) Corporation, and the predicate:

Test	Standard	Result
Force at break	ISO 10555-1	Meets standard
Corrosion resistance	ISO 10555-1	Meets standard
Liquid leakage under pressure	ISO 10555-1	Meets standard
Air leakage into hub assembly during aspiration	ISO 10555-1	Meets standard
Vent fitting	ISO 10555-5	Meets standard
Flow rate	ISO 10555-5	Meets standard
Strength of union between needle hub and needle tube	ISO 10555-5	Meets standard
Gauging	ISO 594-1	Meets standard
Liquid leakage	ISO 594-1	Meets standard
Air leakage	ISO 594-1	Meets standard
Separation force	ISO 594-1	Meets standard
Stress cracking	ISO 594-1	Meets standard

No deviations from recognized consensus ISO standards were identified in the testing to standards.

Performance testing other than to the above ISO Standards was also performed on the device. The device complies with the acceptance criteria for each test:

Performance Test	Results
Cannula and needle hub fitting force	Meets acceptance criteria
Catheter tube and catheter hub fitting force	Meets acceptance criteria
Catheter tube and catheter hub leakage	Meets acceptance criteria
Catheter tube and needle fitting force	Meets acceptance criteria
Flashback	Meets acceptance criteria
Needle and needle hub leakage	Meets acceptance criteria
Needle heel and catheter tip distance	Meets acceptance criteria
Needle penetration	Meets acceptance criteria

Biocompatibility

The TERUMO® SURFLO® I.V. Catheter is classified as:

- Catheter and lubricant: Externally Communicating Device, Circulating Blood, Prolonged Exposure (24 hours to 30 days);
- Cannula with lubricant: Externally Communicating Device, Circulating Blood, Short Term (<24 hours) Use, as the cannula is immediately withdrawn after insertion of the catheter into the vascular system; and
- Catheter hub and caulking pin: Externally Communicating Device, Blood Path Indirect, Prolonged Exposure (24 hours to 30 days).

The device's body and 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 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained all throughout the shelf life of the product. Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Tests
Cytotoxicity
Sensitization
Intracutaneous reactivity
Systemic toxicity (Acute)
Pyrogenicity
Subchronic toxicity (subacute toxicity)
Hemocompatibility
Genotoxicity
Implantation
Physicochemical
Characterization

H. ADDITIONAL SAFETY INFORMATION

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization. The TERUMO® SURFLO® I.V. Catheter is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

I. SUBSTANTIAL EQUIVALENCE (807.92(a)(6))

The TERUMO® SURFLO® I.V. Catheter, manufactured by Terumo (Philippines) Corporation, is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to TERUMO® SURFLO® I.V. Catheter (K891087), manufactured by Terumo Medical Corporation, Elkton, Maryland.

The table on the following page summarizes a comparison of the technological characteristics.

Device	**Terumo (Philippines) Corporation** TERUMO® SURFLO® I.V. catheter **(subject of this 510(k))**	**Terumo Medical Corporation** TERUMO® SURFLO® I.V. catheter (K891087)
Intended Use	Inserted into patient's vascular system for short term use (less than 30 days) to withdraw blood samples, monitor blood pressure, or administer fluids intravenously.	Inserted into patient's vascular system for short term use (less than 30 days) to withdraw blood samples, monitor blood pressure, or administer fluids intravenously (880.5200).
Operation Principle	Manual	Manual
Design / Construction	a. catheter assembly (catheter, caulking pin, and catheter hub) b. needle assembly (needle, needle hub, filter cap and filter)	a. catheter assembly (catheter, caulking pin, and catheter hub) b. needle assembly (needle, needle hub, filter cap and filter)
Material	Cannula – stainless steel Catheter hub – polypropylene Needle hub – polycarbonate Caulking pin – stainless steel Catheter- ETFE with barium sulfate Lubricant – Reactive Silicone	Cannula – stainless steel Catheter hub – polypropylene Needle hub – polycarbonate Caulking pin – stainless steel Catheter- ETFE with barium sulfate Lubricant – Reactive Silicone
Radiopaque Medium	Barium sulfate	Barium sulfate
Color Code of Catheter Hub	In accordance with ISO 10555-5	In accordance with ISO 10555-5
Package	Unit case	Unit case
Sterilization	E-beam radiation (validated in accordance with ISO 11137-1)	EtO (validated in accordance with ISO 11135-1)

J. CONCLUSION (807.92(b)(3))

In summary, the TERUMO® SURFLO® I.V. Catheter, manufactured by Terumo (Philippines) Corporation, is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to TERUMO® SURFLO® I.V. Catheter (K891087), manufactured by Terumo Medical Corporation, Elkton, Maryland.

There is no significant difference that raises any new issues of safety and effectiveness.

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

June 12, 2014

Terumo Medical Corporation
C/O Mr. Phillip Lester
Regulatory Affairs Specialist
950 Elkton Boulevard
Elkton, MD 21921

Re: K133280
Trade/Device Name: Terumo Surflo I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter Short-term
Regulatory Class: II
Product Code: FOZ
Dated: May 16, 2014
Received: May 19, 2014

Dear Mr. Lester:

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" (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 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 yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133280

Device Name

TERUMO® SURFLO® I.V. Catheter or similar proprietary name

Indications for Use *(Describe)*

TERUMO® SURFLO® I.V. Catheter is inserted into the patient's vascular system for short term use (less than 30 days) to withdraw blood samples, monitor blood pressure, or administer fluids intravenously.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman -S
Date: 2014.06.12
11:24:54 -04'00'

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