

K122544

Terumo Corporation  
TERUMO® Surflash® Safety I.V. Catheter 510k  
Section II 510(k) Summary

SEP 5 2012

### 510(k) SUMMARY

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**Date prepared**   : August 1, 2012

**Prepared for**    : Owner/Operator

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Registration Number: 8010026

#### Manufacturer and Sterilization Facility

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**A. DEVICE NAME**

**Proprietary Name**

SURFLASH® Safety I.V. Catheter

**Classification Name**

Intravascular Catheter

Intravascular Catheter (880.5200)

Product Code: FOZ

Panel: General Hospital

Classification: Class II

**Common Name**

Intravascular catheter with needle protection device

**B. INTENDED USE**

The SURFLASH® 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 shaft cover and tip 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. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

**C. DEVICE DESCRIPTION**

**(SUMMARY OF TECHNOLOGICAL CHARACTERISTICS)**

**Principle of Operation/Technology**

The SURFLASH® Safety I.V. Catheter is manually operated and contains a passive safety feature that automatically activates as the needle is withdrawn from the catheter.

### **Design / Construction**

The SURFLASH® Safety I.V. Catheter is a device consisting of catheter assembly (catheter, caulking pin and catheter hub), needle assembly (needle, needle housing, transparent flash chamber with filter and needle protector) and a passive needle-shielding mechanism (shutter and needle shaft cover consisting of inner cylinder, outer cylinder, junction cylinder).

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

Whole length cannula including the sharp end of the inner needle is covered by the needle shielding mechanism as the needle is withdrawn from catheter's hub to aid in the prevention of needle stick injuries.

The grooved cannula which allows the clinician to visualize flashback detection through the groove indicating that there is confirmation of vessel entry is the same as the TERUMO® Surshield®-PUR Safety I.V. Catheter (K100282) and TERUMO® SURFLASH™ I.V. Catheter (K991406).

### **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 catheter that is advanced into the vessel is made of polyurethane which is the same as the TERUMO® Surshield®-PUR Safety I.V. Catheter (K100282) and TERUMO® SURFLASH™ I.V. Catheter (K991406).

### **Specifications**

The SURFLASH™ Safety I.V. Catheter are available in 6 sizes with combination of 18, 20, 22 and 24 gauge catheters diameters and 19, 25 and 32 mm catheters length.

#### D. NON-CLINICAL TESTS

Performance testing was conducted to ensure the safety and effectiveness of the SURFLASH® Safety I.V. Catheter throughout the shelf life, to verify conformity to the applicable part of ISO standards and demonstrate substantial equivalence to the predicate devices as mentioned in the table on next pages.

No new issues of safety and effectiveness were raised with the testing performed. Performance testing demonstrates that the SURFLASH® Safety 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.

A simulated use study was conducted in accordance with FDA's Guidance For Industry and Staff, Medical Devices with Sharps Injury Prevention Features issued on August 9, 2005. The objectives of this study were designed to confirm that study participants are able to read and follow the Instructions for Use to safely and effectively operate the safety feature of the device. The objectives were:

1. Verify that proper activation of the sharps injury prevention feature of the device can be accomplished in simulated clinical environments by healthcare workers who use these types of Safety I.V. Catheters.
2. Determine if the Instructions for Use are adequate for proper activation of the sharps injury prevention feature.

All safety features activated effectively and there were no de-activations after discarding. All participants were able to read and activate the catheter safety feature without further explanation or training. No adverse events occurred.

Conclusion: The safety feature of the device operates safely and effectively as intended. Users with various levels of experience can read the IFU and operate the device safely and effectively.

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| Performance test   | Testing           |              |              |                              |
|--|-------------------|--------------|--------------|------------------------------|
|  | Compliance to ISO |              |              | Testing by internal standard |
|  | ISO 10555-1       | ISO 10555-5  | ISO 23908    |                              |
| Force to needle breaking shutter (Puncture resistance of needle shield)  | Not required      | Not required | X            | Required by ISO              |
| Tensile strength of needle shaft and needle housing (Break strength of safety mechanism)   | Not required      | Not required | X            | Required by ISO              |
| Force to release shutter and reactive force when the shutter opens to cover the cannula tip (Reaction force generated by the activation mechanism) | Not required      | Not required | X            | Required by ISO              |
| Force to detach needle shaft cover from catheter hub (Force to activate safety feature)  | Not required      | Not required | X            | Required by ISO              |
| Simulated maximum pressure   | Not required      | Not required | Not required | X                            |
| Burst pressure ( whole device)   | X                 | Not required | Not required | Required by ISO              |
| Collapse (under negative pressure)   | X                 | Not required | Not required | Required by ISO              |
| Catheter to catheter hub tensile strength (Force at break of catheter / hub)   | X                 | Not required | Not required | Required by ISO              |
| Strength of union between transparent flash chamber (needle connecting part) and needle  | Not required      | X            | Not required | Required by ISO              |
| Needle attachment to catheter (Initial sliding friction)   | Not required      | Not required | Not required | X                            |
| Detection of flashback at catheter tip   | Not required      | Not required | Not required | X                            |
| Detection of flashback at transparent flash chamber (needle connecting part)   | Not required      | X            | Not required | Required by ISO              |
| Flow rate  | Not required      | X            | Not required | Required by ISO              |
| Vent fitting   | Not required      | X            | Not required | Required by ISO              |
| Protector attachment (Drop test)   | Not required      | Not required | Not required | X                            |
| Conical fittings of catheter hub   | X                 | Not required | Not required | Required by ISO              |
| Pressure monitoring  | Not required      | Not required | Not required | X                            |
| Simulated use study  | Not required      | Not required | X            | Required by ISO              |
| Corrosion resistance   | X                 | Not required | Not required | Required by ISO              |
| Catheter body tensile strength (Force at break)  | X                 | Not required | Not required | Required by ISO              |
| Stiffness  | Not required      | Not required | Not required | X                            |
| Elongation   | Not required      | Not required | Not required | X                            |
| Flexural fatigue tolerance   | Not required      | Not required | Not required | X                            |
| Radio-detectability  | Not required      | X            | Not required | Required by ISO              |
| Surface  | X                 | Not required | Not required | Required by ISO              |
| Catheter unit  | Not required      | X            | Not required | Required by ISO              |
| Needle point   | Not required      | X            | Not required | Required by ISO              |

X: Confirmed the conformance to the standard.

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

The TERUMO SURFLASH Safety I.V Catheter is classified as

- Catheter and lubricant: Externally Communicating Device, Circulating Blood, Prolonged Exposure (24hrs – 30 days).
- All other materials contacting with patient’s body: Externally Communicating Devices, Blood path indirect, Prolonged Exposure (24 hrs to 30 days)

As mentioned below table, the device’s materials contacting with patient’s body 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.” Screening tests were performed on accelerated aged whole devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the materials contacting with patient’s body are biocompatible throughout the shelf life of the product.

|                                    |
|------------------------------------|
| Test                               |
| Cytotoxicity                       |
| Sensitization                      |
| Intracutaneous reactivity          |
| Systemic toxicity (acute)          |
| Pyrogen                            |
| Genotoxicity                       |
| Implantation / Subchronic toxicity |
| Hemolysis                          |
| Physicochemical                    |
| Characterization                   |

**E. ADDITIONAL SAFETY INFORMATION**

The sterility of the device is assured using a sterilization method validated in accordance with Method C: Half-cycle method in Annex B of ANSI/AAMI/ISO 11135: Sterilization of health care products – ethylene oxide. The product is sterilized to provide a Sterility Assurance Level (SAL) of  $10^{-6}$ .

## **F. SUBSTANTIAL EQUIVALENCE**

The SURFLASH® Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent to:

1. K100282 Surshield®-PUR Safety I.V. Catheter (Terumo Corporation)
2. K991406 SURFLASH® I.V. Catheter (Terumo Corporation)
3. K971339 BD Insyte™ Autoguard™ shielded I.V. Catheter (Becton Dickinson)
4. K923702 Saf-T-Intima Closed IV Catheter System (Becton Dickinson)

Comparison of the intended use/indication for use statements and technological characteristics are summarized in the following pages.

The minor differences of intended use and the technological differences do not impact the safety and effectiveness of the device in clinical settings.

## **G. CONCLUSION**

The SURFLASH® Safety I.V. Catheter is substantially equivalent to the predicate devices in intended use and technological characteristics.



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 Corporation  
C/O Mr. Mark Job  
Regulatory Technology Services, Limited Liability Company  
1394 25<sup>TH</sup> Street, North West  
Buffalo, Minnesota 55313

SEP 5 2012

Re: K122544  
Trade/Device Name: Surflash<sup>®</sup> Safety I.V. Catheter  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: II  
Product Code: FOZ  
Dated: August 20, 2012  
Received: August 21, 2012

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. 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.

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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 Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Form**

**Indications for Use**

510(k) Number (if known): K122544

Device Name: SURFLASH® Safety I.V. Catheter

Indications for Use:

The SURFLASH® 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 shaft cover and tip 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. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature] 9/4/2012

(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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