K00946

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

AUG 02 2010

Submitter information

Prepared for:	TERUMO EUROPE N.V. Interleuvenlaan 40, 3001 Leuven, BELGIUM
Prepared by/Contact person:	Mrs. M.J. Aerts – Manager Regulatory Affairs Tel. (+32) 16 38 13 53 Fax (+32) 16 40 02 49
Date prepared:	June 2010

1. Device Name

Proprietary Name

SURFLO® Winged Infusion Set with Needle Protection (Surshield™)

Classification Name

Intravascular Administration Set (-FPA)

21 CFR, Section 880.5440

Classification: Class II

2. Reason for Submission

This 510k is being submitted to extend Terumo Europe's cleared Surflo Winged Infusion Set with Needle Protection (Surshield) (K052887 and K072894) product line to include 23G and 25G needle sizes with microbore tubing taking into consideration the potential issues of safety and effectiveness specific for a thinner tubing.
This 510k will provide supporting information that the 23G and the 25G Surflo Winged Infusion Sets with Needle Protection (Surshield) and microbore tubing design are safe and effective and an acceptable extension of the current cleared Surflo Winged Infusion Set with Needle Protection (Surshield) product line (K052887 and K072894).

3. Intended Use

The Surflo Winged Infusion Sets with Needle Protection (Surshield) are intended to access the peripheral vascular system, for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

Note: This is the same intended use as the predicate device, Surflo Winged Infusion Set with Needle Protection (Surshield), cleared under K052887 and K072894.

4. Description

The 23G and the 25G Terumo Surflo Winged Infusion Sets with Needle Protection (Surshield) are sterile, single use devices consisting of a needle attached to a winged hub, microbore tubing, adapter and adapter cap, and a hinged shield cover that attaches to the wing just below the needle-to-wing junction.

The shield cover can be turned 180 degrees on the hinge. As the needle is removed from the patient's vessel, the user's finger actively pushes the shield cover until it latches onto needle using a one- or two-handed technique. An audible click is noted upon activation. The shield cover is designed to allow the user's finger to remain behind the needle point so that the risk of needle stick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

The device possesses a 350 mm length microbore tubing.

5. Substantial Equivalence

The 23G and the 25G Surflo Winged Infusion Sets with Needle Protection (Surshield) with microbore tubing, manufactured by Terumo Europe N.V., submitted in this 510(k) file are substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the following cleared devices:

1. Surflo Winged Infusion Set with Needle Protection (Surshield) (K052887), manufactured by Terumo Europe N.V.
2. Surflo Winged Infusion Set with Needle Protection (Surshield) (K072894), manufactured by Terumo Europe N.V.
3. Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547), manufactured by Terumo Europe N.V.

Any differences between the devices do not raise any significant issues of safety and effectiveness.

Note: For performance testing reference will also be made to the Surflo Winged Infusion Set with Filter and Needle Protection (K070547), as these sets are identical as the sets to be cleared by this submission except for the presence of the filter, consequently their use is limited to infusion.

6. Summary of Technological Modifications compared to Predicate Devices:

The technological modifications made to the subjected device compared to the predicate devices are summarized in the following table:

Predicate device	Modification summary (Proposed device)
Surflo Winged Infusion Set with Needle Protection (Surshield) (K052887) & (K072894)	a) Introduction of microbore tubing b) Adapted design Surshield protector (the connection with the tube remains the same)
Surflo Winged Infusion Set with Filter and Needle Protection (K070547)	a) Use of the same luer adaptor as predicate device BUT without filter b) Adapted design Surshield protector (the connection with the tube remains the same)

7. Summary of Verification Activities:

All necessary verification and validation tests have been performed for the The Surflo Winged Infusion Sets with Needle Protection (Surshield) to assure substantial equivalence to the predicate devices. Summary of all verification activities including acceptance criteria is given in the following table:

TEST	ACCEPTANCE CRITERIA
1. Flow rate	The flow rate for the set with a 23 G needles is ≥ 1.7 ml/min & for a set with a 25 G needles is ≥ 1.5 ml/min
2. Dead space volume	Dead space volume for sets with 23 G & 25G needle ≤ 0.25 ml
3. Air flow choke test	No obstruction of fluid through the set
4. Air leakage set (= Integrity of the set)	No air leakage from the set (European Pharmacopoeia 3.2.6.)
5. Air leakage adapter	No air leakage at the luer fitting (EN 1707)
6. Liquid leakage adapter	No liquid leakage at the luer fitting (EN 1707)
7. Conical fitting	6% luer (EN 20594-1)
8. Fitting strength protector	The force to pull the protector from the wing hub is ≥ 0.3 N and ≤ 12N
9. Torque resistance cap/adapter	The torque force required to unscrew the cap from the adapter is ≤ 9N.cm.
10. Bonding strength Cannula	The bonding strength between the cannula and the wing hub is ≥ 20N
11. Force at break	The force to separate the the tubing from the wing/connector is ≥ 15N
12. Needle penetration resistance	Needle point ≤ 0.14N Drag ≤ 0.03N
13. Break strength of shield cover joint	The force to detach the Surshield protector from the wing hub is ≥ 4N
14. Force to unlock the safety feature	The force required to unlock the Surshield protector from the cannula is ≥ 2N
15. Misalignment Surshield Protector	The angle measured axially from the cannula between the horizontally positioned wings and the vertically positioned Surshield protector does not exceed 15°

The Surflo Winged Infusion Sets with Needle Protection (Surshield) met all acceptance criteria as indicated in table above. None of the obtained data raises any new issue of safety and effectiveness.

8. Additional Safety Information

The sterility of the Surflo Winged Infusion Sets with Needle Protection (Surshield) is assured by using a validated sterilization method qualified in accordance with in accordance with the requirements of EN ISO 11135-1:2007 "Sterilization of health care products – Ethylene oxide – Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices" to a sterility assurance level (SAL) of 10-6 as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The 23G and the 25G Surflo Winged Infusion Sets with Needle Protection (Surshield) are Externally Communicating devices, Circulating Blood, Limited Exposure (24 hrs). The devices' 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 expiration dating for the 23G and the 25G Surflo Winged Infusion Sets with Needle Protection (Surshield) have been established at 5 years which is the same as the cleared Surflo Winged Infusion Sets with Needle Protection (Surshield) (K052887 and K072894).

9. Conclusion

The Surflo Winged Infusion Sets with Needle Protection (Surshield) manufactured by Terumo Europe N.V. and submitted in this 510(k) file are substantially equivalent in intended use, description, specifications, and technology/principles of operation, materials, and performance to the following cleared devices:

1. Surflo Winged Infusion Set with Needle Protection (Surshield) (K052887), manufactured by Terumo Europe N.V.
2. Surflo Winged Infusion Set with Needle Protection (Surshield) (K072894), manufactured by Terumo Europe N.V.
3. Surflo Winged Infusion Set with Filter and Needle Protection (Surshield) (K070547), manufactured by Terumo Europe N.V.

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

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

Ms. M.J. Aerts
Regulatory Affairs Manager
Terumo Europe N.V.
Interleuvenlaan 40
B-3001 Leuven-Belgie
Belgium

AUG 02 2010

Re: K100946
Trade/Device Name: Surflo Winged Infusion Set with Needle Protection (Surshield™)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 1, 2010
Received: July 6, 2010

Dear Ms. Aerts:

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.

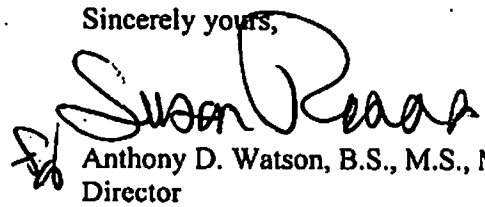
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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

Indication for Use

510(k) Number (if known): K100946

Device Name: Surflo Winged Infusion Set with Needle Protection (Surshield™)

Indication For Use:

The Surflo Winged Infusion Set with Needle Protection (Surshield) is intended to access the peripheral vascular system, for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman

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

510(k) Number: K100946