OCT 1 5 2001

K013164

SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET
Section II - Summary & Certification

SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Device Name: TERUMO® SURSHIELD™ Safety Winged Blood Collection Set

Classification Name: Tubes, vials, systems, serum separators, blood collection
and
Intravascular Administration Sets

Product Code(s): 75 JKA and 80 FPA

B. Reason for Submission:

This premarket notification (510(k)) is being submitted for the SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET, which is blood collection device comprised of two cleared devices both manufactured by Terumo Corporation in Tokyo, Japan. The base predicate device is the SURSHIELD™ SAFETY WINGED INFUSION SET cleared under 510(k) number K010103 and the attached device is the TERUMO® VENOJECT® LUER ADAPTER cleared under 510(k) number K983490. The focus of this submission is to address any potential issues of safety and effectiveness of the device being formed after joining the two cleared devices.

C. Intended Use:

The TERUMO® SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.

The TERUMO® SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is also indicated for intravenous administration of fluids after removing the attached luer adapter from the blood collection set connector and attaching a syringe, or other compatible/appropriate device. This device may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy.

Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Note: This is the same intended use as the predicate device, Surshield Winged Infusion Set – K010103.

D. Description

The Surshield Safety Winged Blood Collection Set is a sterile, single-use device consisting of a needle attached to a winged type hub, tubing, a female connector with a multi-sample luer adapter attached for blood collection. The Surshield Safety Winged Blood Collection Set is the same as the Surshield Safety Winged Infusion Set (K010104) except for the attached luer adapter (K983490).

A hinged safety shield, previously cleared under K010103, is attached to the wing just below the needle-to-wing junction. The safety shield 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 single-handed technique. The shield cover is designed to allow the user's finger to remain behind the needle point so that the risk of needlestick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

E. Substantial Equivalence

The SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is substantially equivalent in intended use, design, technology/principals of operation, materials, and performance to the following cleared devices:

1. TERUMO® SURSHIELD SAFETY WINGED INFUSION SET – K010103
2. TERUMO® VENOJECT® LUER ADAPTER – K983490
3. VACUTAINER® SAFETY-LOK™ BLOOD COLLECTION SET – K980414

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

F. Principals of Operation/Technology

The Surshield Safety Winged Blood Collection Set, Surshield Safety Winged Infusion Set, Venoject Luer Adapter, and Vacutainer Safety-Lok Blood collection set are all operated manually.

G. Materials

The Surshield Safety Winged Blood Collection Set is comprised of the same materials as the cleared Surshield Safety Winged Infusion Set (K010103) and Venoject Luer Adapter (K983490).

H. Specifications

Cannula gauge	Color code	Product code	Cannula length	Tubing length
19G	Cream	MN*SVS19B30	3/4"(19mm)	300mm±10%
		MN*SVS19B18	3/4"(19mm)	180mm±10%
21G	Green	MN*SVS21B30	3/4"(19mm)	300mm±10%
		MN*SVS21B18	3/4"(19mm)	180mm±10%
23G	Light blue	MN*SVS23B30	3/4"(19mm)	300mm±10%
		MN*SVS23B18	3/4"(19mm)	180mm±10%
25G	Orange	MN*SVS25B30	3/4"(19mm)	300mm±10%
		MN*SVS25B18	3/4"(19mm)	180mm±10%

Note: The 180mm length tubing is new for this blood collection device but is bracketed by the 90 and 300mm lengths cleared under K010103.

I. Performance

The following performance tests were performed on the Surshield Safety Winged Blood Collection Set:

- Leakage at connector to luer adapter junction
- Blockage
- Connection strength of luer adapter to connector
- Valve Protector Fit

Additionally, a risk analysis was conducted and any potential issues were addressed through design modification, and/or labeling as appropriate. None of the data raises any new issues of safety and effectiveness.

J. Additional Safety Information

a. Sterilization

The EtO sterilization conditions are validated according to ISO11135/EN550 to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene Oxide residual levels resulting from EtO sterilization will not exceed the maximum residue levels proposed for Part 821 of Title 21 in the Federal Register Notice issued June 23, 1978, and indicated as follows:

Ethylene Oxide	25 ppm
Ethylene Chlorohydrin	25 ppm
Ethylene Glycol	250 ppm

b. Biocompatibility

The device's 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. Results of the testing demonstrate that the blood contacting materials are biocompatible. Therefore, no further testing was deemed necessary.

c. Expiration Dating

Expiration Dating for the Surshield Safety Winged Blood Collection Set will be **36 months (3 years)**.

d. Pyrogen Testing

The Surshield Safety Winged Blood Collection Set is pyrogen free. Testing is performed on each lot of the product using the Limulus Amebocyte Lysate (LAL) gel clot test according to the US Pharmacopoeia XXIV.

K. Conclusion

In summary, the Surshield Safety Winged Blood Collection Set is substantially equivalent in intended use, design, technology/principals of operation, materials, and performance to the following cleared devices:

1. TERUMO® SURSHIELD SAFETY WINGED INFUSION SET – K010103
2. TERUMO® VENOJECT® LUER ADAPTER – K983490
3. VACUTAINER® SAFETY-LOK™ BLOOD COLLECTION SET – K980414

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

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: September 20, 2001

Prepared by: Barbara Smith
Regulatory Affairs Specialist
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Phone#: 410-392-7241
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2001

Ms. Barbara Smith
Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K013164
Trade/Device Name: Surshield™ Safety Winged Blood Collection Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 20, 2001
Received: September 21, 2001

Dear Ms. Smith:

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 such 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.

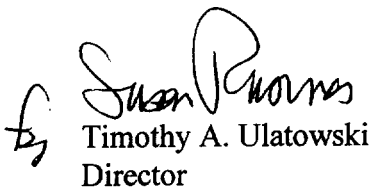
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013164

Device Name: **SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET**

Indications For Use:

The TERUMO® SURSHIELD™ SAFETY WINGED BLOOD COLLECTION SET is a winged blood collection needle intended for venipuncture to collect blood specimens from patients.

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Additionally, after withdraw of the needle from the patient's vein, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off) B. Bolden
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013164

(Optional Format 1-2-96)