

K 991406

JUN 16 1999

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: TERUMO® SURFLO® FLEX I.V. Catheter
TERUMO® SURFLASH™ I.V. Catheter, or similar
proprietary name

Classification Name: Intravascular Catheter

INTENDED USE

The TERUMO® SURFLO® FLEX I.V. Catheters and the TERUMO® SURFLASH™ I.V. Catheters are devices consisting of a slender, flexible, radio-opaque, plastic catheter with a hub that is inserted into the patient's vascular system for short term use to withdraw samples, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors. The stainless steel cannula, placed in the catheter to maintain rigidity, is withdrawn after the catheter is placed in the vascular system.

DESCRIPTION

The TERUMO SURFLO FLEX I.V. CATHETER AND THE TERUMO SURFLASH I.V. CATHETER are sterile, single use devices consisting of a slender tube (catheter) made of polyurethane. The devices are inserted into the patient's vascular system for short-term use to withdraw samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors.

Each device consists of a catheter assembly—catheter, caulking pin, catheter hub; a needle assembly—cannula, needle hub; and a filter cap with an air filter

The catheters are made of polyurethane, which allows appropriate stiffness for proper insertions into the vein, and flexibility during retention in the vein. Each catheter contains barium sulfate radio-opaque stripes along the length of the catheter to allow radio detectability. A stainless steel caulking pin fastens the catheter to the catheter hub.

Each catheter hub is color coded according to the outside diameter as specified in ISO 10555-5, "Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters".

SECTION II: Summary of Safety and Effectiveness

The needle assembly has the same specifications as the Terumo® Surflo® I.V. Catheter, which is the subject of K891087. The transparent needle hubs permit flashback detection when the cannula enters the vessel.

The filter cap with an air filter is provided as a vent fitting.

The Terumo Surflo Flex I.V. Catheter is available in 14 sizes with different combinations of 6 catheter diameters and 5 catheter lengths (see following specifications table). The Terumo Surfflash I.V. Catheter is available in 24G by 19mm currently. Additional sizes will be implemented at a later date.

The cannula of the Surfflash I.V. Catheter are grooved from the heel of the cannula tip bevel to the end of the catheter tip, which allows flashback detection at the catheter tip after the catheter tip enters the vessel.

The only difference between the TERUMO SURFLO FLEX and the TERUMO SURFLASH I.V. catheters is the grooved cannula feature of the SURFLASH. All other specifications are the same.

SPECIFICATIONS/DIMENSIONS

SURFLO FLEX Specification

Catheter gauge	Color code	Product code	Catheter length	Catheter O.D.	Catheter I.D.	Cannula gauge	Flow rate
14G	Orange	SR*OF1451	2" (51mm)	2.17mm	1.73mm	16G	316ml/min
		SR*OF1464	2-1/2" (64mm)				282ml/min
16G	Medium Grey	SR*OF1632	1-1/4" (32mm)	1.70mm	1.30mm	18G	202ml/min
		SR*OF1651	2" (51mm)				184ml/min
		SR*OF1664	2-1/2" (64mm)				177ml/min
18G	Deep Green	SR*OF1832	1-1/4" (32mm)	1.30mm	0.95mm	20G	99ml/min
		SR*OF1851	2" (51mm)				88ml/min
		SR*OF1864	2-1/2" (64mm)				80ml/min
20G	Pink	SR*OF2025	1" (25mm)	1.10mm	0.80mm	22G	73ml/min
		SR*OF2032	1-1/4" (32mm)				67ml/min
		SR*OF2051	2" (51mm)				59ml/min
22G	Deep Blue	SR*OF2225	1" (25mm)	0.85mm	0.60mm	24G	38ml/min
		SR*OF2232	1-1/4" (32mm)				30ml/min
24G	Yellow	SR*OF2419	3/4" (19mm)	0.67mm	0.47mm	27G	15ml/min

SURFLASH Specification

Catheter gauge	Color code	Product code	Catheter length	Catheter O.D.	Catheter I.D.	Cannula gauge	Flow rate
24G	Yellow	SR*FF2419	3/4" (19mm)	0.67mm	0.47mm	27G	15ml/min

SECTION II: Summary of Safety and Effectiveness

SUBSTANTIAL EQUIVALENCE

The TERUMO® SURFLO® FLEX I.V. Catheters and the TERUMO® SURFLASH™ I.V. Catheters, submitted in this 510k, are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Becton Dickinson (B-D®) Insyte® I.V. Catheter and the B-D Insyte (N) I.V. Catheter, which are the subject of K971339 (unable to confirm); and to the Terumo® Surflo® I.V. Catheter which is the subject of K891087.

PRINCIPLE OF OPERATION/TECHNOLOGY

The Terumo SURFLO FLEX and SURFLASH I.V. catheters, the B-D® Insyte and Insyte (N) I.V. catheters, and the Terumo Surflo I.V. catheters are all operated manually.

MATERIALS

COMPONENT	PROPOSED (SURFLO FLEX & SURFLASH)	PREDICATE (TERUMO SURFLO)	PREDICATE (INSYTE & INSYTE (N))
Cannula	Stainless steel	Stainless steel	Stainless steel
Catheter	Polyurethane	Teflon®	Polyurethane
Radio opaque medium	Barium sulfate	Barium sulfate	Barium sulfate
Catheter hub	Polypropylene	Polypropylene	Unknown
Caulking pin	Stainless steel	Stainless steel	Unknown
Filter cap	Polystyrene	Polystyrene	Unknown
Air filter	Polyester	Polyester	Unknown

PERFORMANCE

The performance of the TERUMO® SURFLO® FLEX and the SURFLASH I.V. Catheters is equivalent to the performance of the cleared Becton-Dickinson® (B-D) Insyte® I.V. Catheter, the cleared Becton-Dickinson® (B-D) Insyte® (N) I.V. Catheter (K971339-unable to confirm), and the cleared Terumo Medical Corporation Surflo I.V. Catheter (K891087).

SECTION II: Summary of Safety and Effectiveness

The following tests were performed demonstrating the substantial equivalence of the TERUMO SURFLO FLEX and the SURFLASH I.V. Catheters submitted in this 510k to the B-D Insyte I.V. Catheter, the B-D Insyte (N) I.V. Catheter and the Terumo Surflo I.V. Catheter.

1. Catheter body tensile strength (force at break of catheter)
2. Stiffness
3. Elongation
4. Burst pressure
5. Collapse
6. Flexural fatigue tolerance
7. Radio detectability
8. Flow rate
9. Corrosion resistance of caulking pin
10. Catheter body to catheter hub tensile strength (force at break of catheter/hub)
11. Catheter/needle attachment (fitting strength)
12. Vent fitting
13. Detection of flashback at catheter tip and needle hub
14. Detection of flashback at needle hub
15. Strength of union between needle hub and needle

ADDITIONAL SAFETY INFORMATION

The sterility of the product is assured using a sterilization method validated in accordance with the European Standard, EN 550 (1994): "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization", 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 in the Federal Register Notice issued June 23, 1978, and indicated as follows:

Ethylene oxide	25 ppm
Ethylene chlorhydrin	25 ppm
Ethylene glycol	250 ppm

Manufacturing test methods include functional, chemical stability and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard AAMI/ANSI/ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Guidance on Selection of Tests".

SECTION II: Summary of Safety and Effectiveness

The SURFLO FLEX and SURFLASH I.V. Catheters are classified as external communicating device, circulating blood, prolonged exposure (24 hrs to 30 days).

The expiration dating for the TERUMO® SURFLO® FLEX and the TERUMO® SURFLASH™ will be 60 months.

CONCLUSION

The TERUMO® SURFLO® FLEX I.V. Catheters and the TERUMO® SURFLASH™ I.V. Catheters, submitted in this 510k, are substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Becton Dickinson (B-D®) Insyte® I.V. Catheter and the B-D Insyte (N) I.V. Catheter, which are the subject of K971339 (unable to confirm); and to the Terumo® Surflo® I.V. Catheter which is the subject of K891087. Differences between the devices cited in this section are not significant and do not raise any new issues of safety or effectiveness.

Terumo's statement that these devices are 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	April 19, 1999
Prepared by	Kristine Wagner Regulatory Affairs Specialist
Prepared for	Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Phone (410) 392-7241 or (410) 392-7231 Fax (410) 398-6079



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Ms. Kristine Wagner
Regulatory Affairs Specialist
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, Maryland 21921

Re: K991406
Trade Name: TERUMO® SURFLO® FLEX I.V. CATHETER and
TERUMO® SURFLASH™ I.V. CATHETER
Regulatory Class: II
Product Code: FOZ
Dated: April 19, 1999
Received: April 22, 1999

Dear Ms. Wagner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

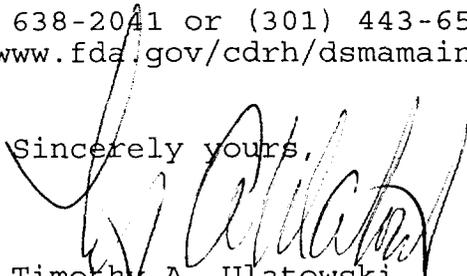
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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): K991406

Device Name: TERUMO® SURFLO® FLEX I.V. CATHETER and TERUMO® SURFLASH I.V. CATHETER

Indications For Use:

The TERUMO® SURFLO® FLEX I.V. Catheters and the TERUMO® SURFLASH™ I.V. Catheters are devices consisting of a slender, flexible, radio-opaque, plastic catheter with a hub. The plastic catheter is inserted into the patient's vascular system for short term use to withdraw samples, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors. The stainless steel cannula, placed in the catheter to maintain rigidity, is withdrawn after the catheter is placed in the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cisente

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

510(k) Number K991406

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____