June 23, 2023

Terumo Medical Products (Hangzhou) Co., Ltd.
% Brian Byrd
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K221411
Trade/Device Name: Surflo Winged Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: June 19, 2023
Received: June 20, 2023

Dear Brian Byrd:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221411

Device Name
Surflo Winged Infusion Set

Indications for Use *(Describe)*
The Surflo Winged Infusion Set is indicated for venipuncture and intravenous administration of fluids for up to 24 hours using compatible/appropriate disposable infusion devices for medical purposes. It may be used for any patient population with consideration given to patient size.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K221411 510(K) SUMMARY

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

Prepared by: Brian Byrd
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Prepared for: ***Owner/Operator***
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Date prepared: June 20, 2023

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

Proprietary Name:	Surflo Winged Infusion Set
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Classification Panel:	General Hospital
Regulation:	21 CFR 880.5440
Product Code:	FPA
Classification:	Class II

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

The legally marketed device to which substantial equivalence is claimed is:

Primary Predicate:

- K771204 – Surflo Winged Infusion Set, manufactured by Kofu Factory of Terumo Corporation.

D. REASON FOR 510(k) SUBMISSION

This Traditional 510(k) is being submitted for the Surflo Winged Infusion Set, an intravascular administration set manufactured by Terumo Medical Products (Hangzhou) Co., Ltd., for the purposes of establishing substantial equivalence to a legally marketed predicate device. The device design remains the same excluding the material of the Connector Cap, available needle lengths, and solvent for the tubing/connector. The remaining components including the needle are the same.

E. INDICATIONS FOR USE (807.92(a)(5))

The Surflo Winged Infusion Set is indicated for venipuncture and intravenous administration of fluids for up to 24 hours using compatible/appropriate disposable infusion devices for medical purposes. It may be used for any patient population with consideration given to patient size.

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

The Surflo Winged Infusion Set consists of a protector, needle, wing, tubing, connector, and connector cap. The connector is 6% female Luer. It is primarily made from medical grade PVC

(the whole device uses TOTM as plasticizer instead of DEHP) and medical grade stainless steel.

The Surflo Winged Infusion Set is operated manually. The device is intended to be used by trained healthcare professionals in a healthcare facility.

The Surflo Winged Infusion Set is available in different gauge sizes and tubing lengths. Table 5.1 shows the available product codes and their specifications.

Table 5.1 Surflo Winged Infusion Set specifications

Product code	Needle gauge (mm)*	Wall thickness**	Needle length (inch)	Tubing length (mm)	Tubing Inner / Outer Diameter (mm)	Priming volume (ml)	Wing type***
SV*18BLK	18G (1.20)	TW	3/4	300	1.2 /2.2	0.45±0.10	C
SV*19BLK	19G (1.10)	TW	3/4	300	1.2 /2.2	0.45±0.10	C
SV*21BLK	21G (0.80)	UTW	3/4	300	1.1/2.1	0.41±0.08	C
SV*22BLK	22G (0.70)	UTW	3/4	300	1.1/2.1	0.41±0.08	C
SV*23BLK	23G (0.65)	UTW	3/4	300	1.1/2.1	0.40±0.08	C
SV*25BLK	25G (0.50)	TW	3/4	300	1.1/2.1	0.40±0.08	C
SV*19BLS	19G (1.10)	TW	3/4	90	1.2/2.2	0.21±0.08	C
SV*21BLS	21G (0.80)	UTW	3/4	90	1.1/2.1	0.20±0.08	C
SV*23BLS	23G (0.65)	UTW	3/4	90	1.1/2.1	0.20±0.08	C
SV*25BLS	25G (0.50)	TW	3/4	90	1.1/2.1	0.19±0.08	C
SV*25EL	25G (0.50)	TW	1/2	200	1.1/2.1	0.30±0.05	D
SV*27EL	27G (0.40)	RW	1/2	200	1.1/2.1	0.30±0.05	D

*Referred to as Needle I/OD in Performance Testing

**TW = Thin Wall, UTW = Ultra-Thin Wall, RW = Regular Wall

***Wing Type: See Figure 11.1 in Section 11 – Device Description for differences in dimensions

The Surflo Winged Infusion Set is a disposable device intended for single use only. The device is packaged and sterilized by ethylene oxide gas.

Mechanical Specifications applicable to the Surflo Winged Infusion Set:

Table 5.2 Strength of material (body-contacting material)

	Tensile stress strength when 100% elongated	**Tensile fracture strength**
PVC (TR-630T)【tubing】	5.84±1.96 MPa	17.3±4.9 MPa

PVC (R-500T)【wing】	10.3±2.9 MPa	22.2±5.9 MPa
	Izod impact strength	
PMMA【connector】	>68.6J/m	

Tubing elongation: 410~490%

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The Surflo Winged Infusion Set, subject of this 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the Surflo Winged Infusion Set (K771204), manufactured by Kofu Factory of Terumo Corporation, Japan.

A comparison of the technological characteristics is summarized in the table below:

Table 5.3: Summary of Comparative Information

Device Characteristic	**Subject Device:** Surflo Winged Infusion Set	**Predicate:** Surflo Winged Infusion Set, K771204
Manufacturer	Terumo Medical Products (Hangzhou) Co., Ltd.	Terumo Corporation
Intended Use	The Surflo Winged Infusion Set is a device used to administer fluids from a container to a patient's vascular system through a needle inserted in a vein.	Same
Indications for Use	The Surflo Winged Infusion Set is indicated for venipuncture and intravenous administration of fluids for up to 24 hours using compatible/appropriate disposable infusion devices for medical purposes. It may be used for any patient population with consideration given to patient size.	The Surflo Winged Infusion Set is a device used to administer fluids from a container to a patient's vascular system through a needle inserted in a vein. The product consists of a needle with attached tubing and connectors.
Operation Principle	Manual	Same

Device Characteristic	**Subject Device:** Surflo Winged Infusion Set	**Predicate:** Surflo Winged Infusion Set, K771204
Design / Construction	• Needle, needle protector, winged type hub, tubing, connector, connector cap	Same
Materials	• Needle: stainless steel • Needle protector: Polyethylene • Wing: PVC • Tubing: PVC • Connector: PMMA • Connector cap: Polypropylene	• Needle: Same • Needle protector: Same • Wing: Same • Tubing: Same • Connector: Same • Connector cap: Polyethylene or Polypropylene
Package	• Primary pack • Shelf box • Shipping carton	Same
Specifications	Needle Gauge: 18G, 19G, 21G, 22G, 23G, 25G, 27G Needle Length (inch): ¾", ½" Tubing Length (mm): 300, 90, 200	Needle Gauge: 18G, 19G, 21G, 22G, 23G, 25G, 27G Needle Length (inch): ¾ ", ¼ ", ½ ", 1" ,1¼" Tubing Length (mm): 300, 90, 200
Sterilization	Ethylene oxide (validated in accordance with ISO 11135 to achieve SAL 10^{-6})	Same
Shelf Life	3 years	Same

Note:

- The subject device needle lengths fall within the range of the predicate device's cleared needle lengths. Therefore, the product is substantially equivalent because no new needle lengths were introduced.

- The indications for use of the K771204 cleared product is essentially the same as the subject device except for the inclusion of the patient population statement and

duration for use. The patient population statement was added because the predicate does not identify the intended patient population. This statement aims to direct the user to be mindful of the patient size so the patient can be administered intravenous therapy safely. While the predicate did not specify duration for use, the duration for use was added to clarify the period where the product can be safely used. Although there are wording differences within the statements, the intended use for the subject and the predicate devices are the same.

The Surflo Winged Infusion Set, manufactured by Terumo Medical Products (Hangzhou) Co., Ltd., is substantially equivalent to K771204 Surflo Winged Infusion Set, manufactured by Kofu Factory of Terumo Corporation.

H. NON-CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the Surflo Winged Infusion Set met the predetermined specifications throughout the shelf life, verify conformity to the applicable parts of ISO and non-ISO standards, and demonstrate substantial equivalence to the predicate device. No new issues of safety and effectiveness were raised with the testing performed. The following performance tests were performed on the Surflo Winged Infusion Set:

Table 5.4: Performance Tests

Test	Standard
Flow rate	GB 18671-2009 *Intravenous needles for single use*
Leak test	JIS T 3222:2011 *Sterile winged intravenous devices*
Wing to tubing connection strength (static pull force)	ISO 8536-4:2019 *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*
Tubing to connector connection strength (static pull force)	ISO 8536-4:2019 *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*
Needle to wing connection strength (static pull force)	ISO 8536-4:2019 *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*
Needle curvature	JIS T 3222:2011 *Sterile winged intravenous devices*

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

Additionally, performance testing other than to the above ISO and non-ISO Standards was performed on the device. The device complies with the acceptance criteria established based on the predicate device:

Table 5.5: Additional Performance Tests

Performance Test	Results
Wing to tubing connection strength (dynamic pull force)	Meets acceptance criteria
Tubing to connector connection strength (dynamic pull force)	Meets acceptance criteria
Needle to wing connection strength (dynamic pull force)	Meets acceptance criteria
Wing-needle protector fit	Meets acceptance criteria
Needle penetration resistance	Meets acceptance criteria
Blockage test	Meets acceptance criteria

Performance Test	Results
Priming volume	Meets acceptance criteria

Performance testing demonstrates that the Surflo Winged Infusion Set conforms to the recognized consensus ISO and non-ISO standards, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout the shelf life.

Biocompatibility

In accordance with ISO 10993-1, the Surflo Winged Infusion Set is classified as: Externally Communicating Device, Blood Path, Indirect, Prolonged Contact (>24 hours to 30 days). This classification was chosen as "worst case scenario," and is the same as the Surflo Winged Infusion Set, K771204. The finished device's patient contacting parts were tested in accordance with the tests recommended in FDA *Guidance for Industry and Food and Drug Administration Staff – Use of International Standard ISO-10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The tests were performed on non-aged (time=0) and accelerated-aged devices to show that biocompatibility is maintained throughout the shelf life of the product. **Table 5.6** provides a list of biocompatibility tests conducted on the Surflo Winged Infusion Set.

Table 5.6: Summary of ISO 10993 Biocompatibility Testing

Non-Aged, Sterile, Whole Device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute System Toxicity
Pyrogenicity
Hemolysis
Subacute/Subchronic Toxicity
Accelerated-Aged (3 Years), Sterile, Whole Device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute System Toxicity
Pyrogenicity
Hemolysis
Subacute/Subchronic Toxicity

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide —Requirements for the development, validation and routine control of a sterilization process for medical devices*. The Surflo Winged Infusion Set is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

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

In summary, the Surflo Winged Infusion Set, subject of this 510(k), is Substantially Equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device K771204 – Surflo Winged Infusion Set manufactured by Kofu Factory of Terumo Corporation.