



December 17, 2025

Terumo Medical Products (Hangzhou) Co., Ltd.
Tien Trinh
Regulatory Affairs Specialist II
Terumo Medical Corporation
265 Davidson Avenue
Suite 320
Somerset, New Jersey 08873

Re: K252398

Trade/Device Name: SURFLO Hybria Closed System Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: November 19, 2025
Received: November 19, 2025

Dear Tien Trinh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colleen J. Lawrimore -S

Colleen Lawrimore, Ph.D.

For 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

Indications for Use

510(k) Number (if known)

K252398

Device Name

SURFLO Hybria Closed System Safety IV Catheter

Indications for Use (Describe)

SURFLO Hybria Closed System Safety IV Catheter is intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. The device may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. When the device is used with a power injector, the needle-free connector should be removed, and the maximum pressure limit is 325 psi (2.24MPa).

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.

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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

510(k) SUMMARY – K252398

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

Prepared by: Tien Trinh
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Prepared for: *Owner/Operator*
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Registration Number: 3004102031

Manufacturer and Sterilization Facility (Applicant)
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M4-9-5, Hangzhou Economic & Technological Development
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Registration Number: 3004102031

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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

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E-mail: tien.trinh@terumomedical.com

Date prepared: December 17, 2025

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

Trade Name: SURFLO Hybria Closed System Safety IV Catheter
Common Name: Catheter, intravascular, therapeutic, short-term less than 30 days
Classification Name: Intravascular Catheter
Classification Panel: General Hospital
Regulation Number: 21 CFR 880.5200
Product Code: FOZ
Device Class: Class II

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

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

- Predicate Device: K102520- BD Nexiva™ Closed IV Catheter System

D. REASON FOR 510(k) SUBMISSION

This Traditional 510(k) for the SURFLO Hybria Closed System Safety IV Catheter, manufactured by Terumo Medical Products (Hangzhou) Co., Ltd is being submitted to establish substantial equivalence to a legally marketed predicate device.



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

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

SURFLO Hybria Closed System Safety IV Catheter is an over-the-needle intravascular catheter. It primarily includes a catheter, a 3D-Shin™ needle with a safety shield, double wings, an extension tube, a luer adapter, vent fitting(s), and a pre-attached SURPLUG™ AD needle-free connector (for some configurations).

The double wings of the SURFLO Hybria Closed System Safety IV Catheter can be folded and pinched together for puncture and catheter advancement. The distance from the grip position to the needle tip is short, which facilitates vascular puncture. The 3D-Shin™ needle features an engineered three-dimensional geometry of the needle tip. The needle tip is completely covered by the safety shield when it is withdrawn after visualization of blood return, which minimizes the risk of accidental needlestick injury. The closed design can prevent blood leakage throughout the entire puncture process.

Design/Construction

The subject device and the predicate device- BD Nexiva™ Closed IV Catheter System (K102520) have the same construction.



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

Materials

The Materials for the subject device are provided in **Table 1**.

Table 1: List of Material

No.	Name of Component	Raw Material
1**	Catheter	Polyurethane
2	Catheter (Radiopaque layer)	Polyurethane+Barium Sulfate
3*	Catheter hub	Polycarbonate
4*	Needle	Stainless steel
5*	Rivet pin	Stainless steel
6*	Seal gum	Isoprene rubber
7	Safety shield	Stainless steel
8	Needle hub	Polycarbonate
9	Wing	Polyurethane
10*	Extension tube	Polyurethane
11*	Y Luer connector	Copolyester
12*	I Luer connector	Copolyester
13 *	Needle-free connector	Polypropylene and silicone rubber
14	Vent fitting	Polystyrene
15	Clamp	POM
16	Protective caps	Polypropylene
17	Silicone Oil	NCT 911, ELEMENT14*PDMS 30K-J
18	UV Adhesive	LOCTITE 3301

* Blood Path, Indirect, **Circulating Blood



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

Specifications

The specifications for the subject device are provided in **Table 2**.

Table 2: SURFLO Hybria Closed System Safety IV Catheter Specifications

Catheter gauge	Needle gauge	Product code	Catheter OD× length	Infusion connector type	ID of extension tube		
18G	20G	SH18322332AF	18G×1 ¹ / ₄ " (1.3mm×32mm)	Dual Port, 1 vent fitting, 2 needle-free connectors			
		SH18252332AF	18G×1" (1.3mm×25mm)				
		SH18192332AF	18G× ³ / ₄ " (1.3mm×19mm)				
20G	22G	SH20322332AF	20G×1 ¹ / ₄ " (1.1mm×32mm)				
		SH20252332AF	20G×1" (1.1mm×25mm)				
		SH20192332AF	20G× ³ / ₄ " (1.1mm×19mm)				
22G	24G	SH22252332AF	22G×1" (0.9mm×25mm)				
		SH22192332AF	22G× ³ / ₄ " (0.9mm×19mm)				
24G	27G	SH24192332AF	24G× ³ / ₄ " (0.7mm×19mm)				
		SH24132332AF	24G× ¹ / ₂ " (0.7mm×13mm)				
18G	20G	SH18322331AF	18G×1 ¹ / ₄ " (1.3mm×32mm)			Dual Port, 1 vent fitting, 1 needle-free connector	
		SH18252331AF	18G×1" (1.3mm×25mm)				
		SH18192331AF	18G× ³ / ₄ " (1.3mm×19mm)				
20G	22G	SH20322331AF	20G×1 ¹ / ₄ " (1.1mm×32mm)				
		SH20252331AF	20G×1" (1.1mm×25mm)				
		SH20192331AF	20G× ³ / ₄ " (1.1mm×19mm)				
22G	24G	SH22252331AF	22G×1" (0.9mm×25mm)				
		SH22192331AF	22G× ³ / ₄ " (0.9mm×19mm)				
24G	27G	SH24192331AF	24G× ³ / ₄ " (0.7mm×19mm)				
		SH24132331AF	24G× ¹ / ₂ " (0.7mm×13mm)				
18G	20G	SH18322333AF	18G×1 ¹ / ₄ " (1.3mm×32mm)	Dual port, 2 vent fittings	1.6mm		
		SH18252333AF	18G×1" (1.3mm×25mm)				
		SH18192333AF	18G× ³ / ₄ " (1.3mm×19mm)				
20G	22G	SH20322333AF	20G×1 ¹ / ₄ " (1.1mm×32mm)				
		SH20252333AF	20G×1" (1.1mm×25mm)				



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SURFLO Hybria Closed System Safety IV Catheter

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Catheter gauge	Needle gauge	Product code	Catheter OD× length	Infusion connector type	ID of extension tube
		SH20192333AF	20G× ³ / ₄ " (1.1mm×19mm)	Single port, 1 vent fitting	
22G	24G	SH22252333AF	22G×1" (0.9mm×25mm)		
		SH22192333AF	22G× ³ / ₄ " (0.9mm×19mm)		
24G	27G	SH24192333AF	24G× ³ / ₄ " (0.7mm×19mm)		
		SH24132333AF	24G× ¹ / ₂ " (0.7mm×13mm)		
18G	20G	SH18322320AF	18G×1 ¹ / ₄ " (1.3mm×32mm)		
		SH18252320AF	18G×1" (1.3mm×25mm)		
		SH18192320AF	18G× ³ / ₄ " (1.3mm×19mm)		
20G	22G	SH20322320AF	20G×1 ¹ / ₄ " (1.1mm×32mm)		
		SH20252320AF	20G×1" (1.1mm×25mm)		
		SH20192320AF	20G× ³ / ₄ " (1.1mm×19mm)		
22G	24G	SH22252320AF	22G×1" (0.9mm×25mm)		
		SH22192320AF	22G× ³ / ₄ " (0.9mm×19mm)		
24G	27G	SH24192320AF	24G× ³ / ₄ " (0.7mm×19mm)		
		SH24132320AF	24G× ¹ / ₂ " (0.7mm×13mm)		
18G	20G	SH18322321AF	18G×1 ¹ / ₄ " (1.3mm×32mm)	Single port, 1 vent fitting, 1 needle-free connector	
		SH18252321AF	18G×1" (1.3mm×25mm)		
		SH18192321AF	18G× ³ / ₄ " (1.3mm×19mm)		
20G	22G	SH20322321AF	20G×1 ¹ / ₄ " (1.1mm×32mm)		
		SH20252321AF	20G×1" (1.1mm×25mm)		
		SH20192321AF	20G× ³ / ₄ " (1.1mm×19mm)		
22G	24G	SH22252321AF	22G×1" (0.9mm×25mm)		
		SH22192321AF	22G× ³ / ₄ " (0.9mm×19mm)		
24G	27G	SH24192321AF	24G× ³ / ₄ " (0.7mm×19mm)		
		SH24132321AF	24G× ¹ / ₂ " (0.7mm×13mm)		



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

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

SURFLO Hybria Closed System Safety IV Catheter is intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. The device may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. When the device is used with a power injector, the needle-free connector should be removed, and the maximum pressure limit is 325 psi (2.24MPa).

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

The SURFLO Hybria Closed System Safety IV Catheter, subject of this Traditional 510(k), is substantially equivalent¹ in its intended use/indications for use, technology/principal of operation, materials, and performance to BD Nexiva™ Closed IV Catheter System (K102520), manufactured by Becton Dickinson Infusion Therapy Systems, Inc.

A comparison of the technological characteristics is summarized in **Table 3**

¹ A statement of substantial equivalence to another product is required by 21CFR807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, *et seq.* (1977)



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

Table 3: Comparison of Technological Characteristics

Device Characteristic	Subject Device: SURFLO Hybria Closed System Safety IV Catheter	Predicate Device: BD Nexiva™ Closed IV Catheter System (K102520)	Same/Different Assessment
<i>Indications for Use</i>	SURFLO Hybria Closed System Safety IV Catheter is intended to be inserted into a patient’s peripheral vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids. The device may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. When the device is used with a power injector, the needle-free connector should be removed, and the maximum pressure limit is 325 psi (2.24MPa).	BD Nexiva™ Closed IV Catheter Systems are intended to be inserted into a patient’s peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	Although the wording differs here, both devices may be used with power injectors and require the removal of connectors/access ports prior to use with a power injector. However, the maximum pressure limit for the subject device is 325 psi, while the predicate’s is 300 psi. The 325 psi value for the subject device was selected to align with clinically used power injectors, which commonly have a pressure limit of 325 psi. This difference does not raise any new questions of safety and effectiveness of the device based on the performance test results.



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

<i>Operation Principle</i>	Manual	Same	Same
<i>Design / Construction</i>	<ul style="list-style-type: none"> • Catheter assembly (catheter, catheter hub, needle, needle hub), extension tube, safety shield • In accordance with ISO 10555-1 	<ul style="list-style-type: none"> • Catheter assembly (catheter, catheter hub, needle, needle hub), extension tube, safety shield • In accordance with ISO 10555-1 	Same
<i>Materials</i>	<ul style="list-style-type: none"> • Catheter – Polyurethane • Catheter Hub – Polycarbonate • Needle – Stainless Steel • Needle hub – Polycarbonate • Extension tube – Polyurethane • Safety shield – Stainless Steel 	<ul style="list-style-type: none"> • Catheter – Polyurethane • Catheter Hub – Copolyester • Needle – Stainless Steel • Needle hub – Polycarbonate • Extension tube – Polyurethane • Safety shield – Polycarbonate + stainless steel 	Although the material differs, Terumo has conducted chemical characterization and biocompatibility tests, and the results confirm that the material poses no chemical or biological safety concerns. This difference does not raise any new questions of safety and effectiveness.
<i>Package</i>	<ul style="list-style-type: none"> • Blister • Shelf box • Shipping carton 	<ul style="list-style-type: none"> • Blister • Shelf box • Shipping carton 	Same
<i>Catheter Gauge</i>	18G, 20G, 22G, 24G	Same	Same



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510(k) Summary

<i>Sterilization</i>	EO (validated in accordance with ISO 11135 to achieve SAL 10 ⁻⁶)	Same	Same
<i>Shelf life</i>	3 Years	Same	Same
<i>MRI Safety</i>	MR Conditional	Same	Same



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510(k) Summary

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

Performance

Performance testing was conducted to ensure that the SURFLO Hybria Closed System Safety IV Catheter is as substantially equivalent to the predicate device throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate that the device is MR Conditional. The following performance tests were performed on both non-aged and/or accelerated-aged samples. **Table 4** provides a list of the performance tests that were performed on the SURFLO Hybria Closed System Safety IV Catheter.

Table 4: Summary of Performance Tests

Test Item
Safety mechanism activation
Needle tip exposure in safe mode
Force to push needle back through safety mechanism
Safety mechanism unintentional activation
Penetration resistance
Protective caps
Clamps
Engagement and disengagement of clamp
Needle/needle hub bonding strength (static and dynamic)
Needle-free connector-leakage
Needle-free connector- access times
Tensile strength of extension tube (static and dynamic)
Catheter collapse
Tip flexural fatigue
Simulated Clinical Use
MRI Compatibility Test
Radiopacity Test
Particle Contamination



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510(k) Summary

Microbial Ingress
Luer Connector

MRI Compatibility Testing

MRI Compatibility testing was performed on the SURFLO Hybria Closed System Safety IV Catheter finished device without the needle. Testing was performed in accordance with the tests recommended in the FDA *Guidance for Industry and Food and Drug Administration Staff, “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”* to obtain MR Conditional safety information. **Table 5** below lists MRI tests conducted on the SURFLO Hybria Closed System Safety IV Catheter.

Table 5: Summary of MRI Tests Performed

Test Items	Applicable Standards
Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	ASTM F2052-21
Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	ASTM F 2213-2017
Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	ASTM F2119-07(2013)

Performance testing for t=0 and t=36AA (3-year accelerated age) and the MRI Compatibility Testing demonstrated that the predetermined acceptance criteria were met, that the SURFLO Hybria Closed System Safety IV Catheter is acceptable for clinical use throughout its shelf life, and that the device is MR Conditional.

Biocompatibility Classification

In accordance with ISO 10993-1, the SURFLO Hybria Closed System Safety IV



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510(k) Summary

Catheter is classified as Externally Communicating Device, Circulating Blood, Prolonged Exposure (24 hours to 30 days).

Biocompatibility Testing

The finished device’s blood/body contacting parts were tested in accordance with the tests recommended in the FDA Guidance: Use of International Standard ISO 10993-1, “*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process*”. Screening tests were performed on non-aged and accelerated-aged devices to show that biocompatibility is maintained throughout the shelf life of the product. **Table 6** provides a list of biocompatibility testing conducted on the SURFLO Hybria Closed System Safety IV Catheter.

Table 6: Biocompatibility Tests

Non-aged, Sterile, Whole Device	Applicable Standard
Genotoxicity	ISO 10993-3:2014
Implantation	ISO 10993-6:2016
Hemocompatibility	ISO 10993-4:2017
Cytotoxicity	ISO 10993-5:2009
Subacute Toxicity	ISO 10993-11:2017
Sensitization	ISO 10993-10:2021
Irritation or Intracutaneous Reactivity	ISO 10993-23:2021
Acute System Toxicity	ISO 10993-11:2017
Complement Activation	ISO 10993-4:2017
Pyrogenicity	ISO 10993-11:2017
Accelerated age (36-months (3 years)), Sterile, Whole Device	Applicable Standard
Cytotoxicity	ISO 10993-5:2009
Irritation or Intracutaneous Reactivity	ISO 10993-23:2021
Acute System Toxicity	ISO 10993-11:2017

The testing results demonstrate that the device is biocompatible throughout the



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SURFLO Hybria Closed System Safety IV Catheter

510(k) Summary

product's shelf life.

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 Hybria Closed System Safety IV Catheter 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 Hybria Closed System Safety IV Catheter, subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device BD Nexiva™ Closed IV Catheter System (K102520), manufactured by Becton Dickinson Infusion Therapy Systems, Inc.