



Food and Drug Administration
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December 01, 2015

Terumo Medical Corporation
Erin Doyle
Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, MD 21921

Re: K152173

Trade/Device Name: Glidesheath™
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 29, 2015
Received: October 30, 2015

Dear Mr. Doyle:

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 contact the Division of Industry and Consumer Education 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>. 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 <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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman", is written over a large, faint, light-colored watermark of the FDA logo.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name
Glidesheath™

Indications for Use (Describe)

The Glidesheath™ is indicated to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

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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SECTION 5 – 510(k) SUMMARY

A summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

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510(K) SUMMARY

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

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Prepared for: *Owner/Operator*
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Date prepared: July 31, 2015

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

Proprietary Name: Glidesheath™
Common Name: Introducer Sheath
Classification Name: Introducer, Catheter
Classification Panel: Cardiovascular
Regulation: 21 CFR 870.1340
Product Code: DYB
Classification: Class II

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

The legally marketed device(s) to which substantial equivalence is/are claimed is/are:

- K082644, – Glidesheath™ manufactured by manufactured by Terumo Corporation, Japan.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted due to the addition of a new manufacturing site for the Glidesheath™ (K082644) currently manufactured by Terumo Corporation (Ashitaka, Japan facility). The Glidesheath™ design, technology, and manufacturing is being transferred from its current manufacturing site, Terumo Corporation (Ashitaka, Japan facility) to Terumo Medical Corporation (Elkton, Maryland facility). The Ashitaka facility of Terumo Corporation will continue to manufacture the Glidesheath.

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

Principle of Operation Technology

The proposed Glidesheath™ manufactured by Terumo Medical Corporation (TMC) and the predicate Glidesheath (K082644) manufactured by Terumo Corporation (TC) are operated manually or by a manual process.

Design/Construction

The Glidesheath consists of an introducer (sheath and dilator), which are packaged together with a mini guide wire. Some product configurations also include an entry needle, guide wire inserter and a flushing syringe. The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel. In addition, the sheath and dilator contain bismuth, making these devices visible under fluoroscopy.

The entry needle (cannula) is used to gain access to the vein or artery for placement of the mini guide wire. The entry needle is offered in either stainless steel (SS) version or the Surflo (SR) IV catheter (which includes a needle) (K891087). There are two different types of stainless steel entry needles that are available in various gauges and lengths.

The mini guide wire is inserted through the cannula into the patient's blood vessel and is used for placement of the sheath and dilator into the vein or artery. A guide wire inserter is provided to assist in insertion of the mini guide wire into the cannula. The mini guide wire is offered in three versions, either a stainless steel spring coil model (stainless steel), a nitinol model with palladium tipped (nitinol) or a polyurethane plastic model with a nitinol core (plastic).

Following guide wire insertion, the cannula is removed and the sheath and dilator are then inserted over the mini guide wire and into the blood vessel. The mini guide wire is then withdrawn from the vessel. The dilator maintains the integrity of the sheath and dilates the blood vessel during insertion. Once the sheath is situated in the vessel, the dilator is removed and an appropriate catheter can then be inserted through the sheath. The flushing syringe is used to prime the dilator with heparinized saline.

The entry needle, the mini guide wire, the guide wire inserter and flushing syringe, are all accessories to the Glidesheath. Depending on the product code, certain accessories may or may not be contained within the kit. All of the accessories for a given product code are provided in an individual package with the Glidesheath and sterilized together.

Materials

Table 5.1 below provides an overview of the materials of the proposed TMC Glidesheath.

Table 5.1: Proposed TMC Glidesheath Materials

Glidesheath Component		Material
Sheath	Tube	Ethylene-Tetrafluoroethylene (ETFE) copolymer, Bismuth Trioxide
	Hydrophilic Coating	Dimethyl acrylamide-glycidyl methacrylate copolymer
	Housing	Polypropylene
	Caulking Pin	Stainless Steel
	Cap	Polypropylene
	Valve	Silicone Rubber
	Sheath Support	Styrene-ethylene-butylene-styrene block copolymer
	Side Tube	Polybutadiene
	3-Way Stopcock	Polyethylene, Polypropylene, Polycarbonate
Dilator	Tube	Polypropylene, Bismuth subcarbonate
	Hub	Polypropylene
	Caulking Pin	Stainless Steel
Plastic Jacketed Guide Wires		Nickel-Titanium alloy, Tungsten, Polyurethane
Stainless Steel Straight and J-Tip Guide Wires		Stainless Steel
Nitinol Guide Wire		Nickel-Titanium alloy, Palladium
Guide Wire Inserter		Polyethylene
TPC Stainless Steel Entry Needle	Cannula	Stainless Steel
	Hub	Polycarbonate

Glidesheath Component		Material
TRI Stainless Steel Entry Needle	Cannula	Stainless Steel
	Hub	Styrene-butadiene
Surflo IV Catheter	Catheter tube	Ethylene-Tetrafluoroethylene (ETFE) copolymer, Barium sulfate
	Hub	Polypropylene
	Caulking Pin	Stainless Steel
	Filter Cap	Polystyrene, Polyester-Chlorinated polyvinyl chloride
	Adapter	Polypropylene
	Needle Cannula	Stainless Steel
	Needle Hub	Polycarbonate
Flushing Syringe	Barrel	Polypropylene
	Plunger	Polypropylene
	Gasket	Rabalon

Specifications

Table 5.2 below provides an overview of the device specifications for the proposed TMC Glidesheath.

Table 5.2: Proposed TMC Glidesheath Specifications

Component	Parameter	Specification		
		4Fr	5Fr	6Fr
Sheath	Size	4Fr	5Fr	6Fr
	Length	10,16, 25 (cm)		
	Hydrophilic coating	10,16, 25 (cm) - entire length of sheath		
Dilator	Applicable to GW Outer Diameter	0.021, 0.025 (inch)		0.021,0.025 0.035 (inch)
	Length	15.7, 21.7, 30.7cm		
Guide Wire (Stainless Steel)	Outer Diameter	0.021 (inch)	0.021, 0.025 (inch)	0.021,0.025 0.035(inch)
	Length	45, 80 (cm)		
Guide Wire (Nitinol)	Outer Diameter	n/a	0.021 (inch)	
	Length	n/a	45 (cm)	
Guide Wire (Plastic)	Outer Diameter	0.021, 0.025 (inch)		
	Length	45 (cm)	45, 80 (cm)	
Surflo IV Catheter	Type	20, 22 (G)		
	Length	25,32 (mm) – 1, 1 ^{1/4} (inch) (20G x 32mm, 22G x 25mm)		
	Type	n/a	20, 21 (G)	

TPC Stainless Steel Entry Needle	Length	n/a	35 (mm) (1 2/5")
TRI Stainless Steel Entry Needle	Type	n/a	21 (G)
	Length	n/a	38 (mm) (1 1/2")
Flushing Syringe	Volume	2.5mL	

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

The Glidesheath is indicated to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

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

The proposed Glidesheath manufactured by Terumo Medical Corporations, subject of this 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the predicate Glidesheath, manufactured by Terumo Corporation.

Table 5.3 below provides a summary comparison of the proposed TMC Glidesheath and the predicate TC Glidesheath (K082644).

Table 5.3: Summary of Substantial Equivalence

Device Characteristic	Proposed TMC Glidesheath	Predicate TC Glidesheath (K082644)
Manufacturer	Terumo Medical Corporation (Elkton, MD)	Terumo Corporation (Ashitaka, Japan)
Intended Use / Indications for Use	The Glidesheath is indicated to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.	<p>The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.</p> <p>The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery including but not limited to the radial artery.</p> <p>The Radifocus Obturator is also an accessory device which is used</p>

Device Characteristic	Proposed TMC Glidesheath		Predicate TC Glidesheath (K082644)
			by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery, including but not limited to the radial artery, after removal of a catheter.
Operation Principle	Manual		same
Design / Specifications	<u>Introducer (4,5,6 Fr):</u> <ul style="list-style-type: none"> • Hydrophilic Sheath • Dilator <u>Accessories:</u> <ul style="list-style-type: none"> • Guide Wires - 0.021,0.025 0.035 (inch) • Needles – 20G, 21G, 22G • Flushing Syringe – 2.5mL • Guide Wire Inserter 		same
Performance	The proposed TMC Glidesheath design and performance specifications are based off of the same internal and external standards as the predicate TC Glidesheath (K082644)		same
Materials	Sheath	ETFE copolymer, Bismuth Trioxide, Dimethyl acrylamide-glycidyl methacrylate copolymer, Polypropylene, Stainless Steel, Silicone Rubber, Styrene-ethylene-butylene-styrene block copolymer, Polybutadiene, Polycarbonate, Polyethylene	same
	Dilator	Polypropylene, Bismuth subcarbonate, Stainless Steel	
	Plastic Jacket Guide Wire	Nickel-Titanium alloy, Polyurethane, Tungsten	
	SS Guide	Stainless Steel	

Device Characteristic	Proposed TMC Glidesheath		Predicate TC Glidesheath (K082644)
	Wire		
	Nitinol Guide Wire	Nitinol, Palladium, Epoxy	Wire not available in kits for predicate TC Glidesheath (K082644). Identical wire included in kit for reference Glidesheath (K102008).
	Guide Wire Insert	High Density Polyethylene	same
	SR Catheter	ETFE copolymer, Barium sulfate, Polypropylene, Stainless Steel, Polystyrene, Polyester-Chlorinated polyvinyl chloride, Polycarbonate	same
	SS Needle	Stainless Steel, Polycarbonate	same
	Siliconized SS Needle	Stainless Steel, styrene-butadiene	Needle not available in kits for predicate Glidesheath (K082644). Identical needle included kit for reference Glidesheath (K102008)
	Syringe	Polypropylene, Resin: Rabalon	same
Packaging	Tyvek, Polyester-polyethylene laminated film, High Impact Polystyrene		same
Sterilization Method	Ethylene oxide sterilization (validated in accordance with ISO 11137-1 to achieve SAL 10 ⁻⁶)		same

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

Performance

Performance testing was conducted to ensure the proposed TMC Glidesheath met the applicable design and performance requirements throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. **Tables 5.4 – 5.9** below provide a list of the performance tests that were performed on the proposed TMC Glidesheath.

Table 5.4: Summary of Sheath Performance Testing

Component	Test Description	Standard
Sheath	Visual Inspection – Extraneous matter	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Process and surface defects	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Lubricant on external surfaces	ISO 11070: 1998, Sect. 4.3
	Corrosion Resistance	ISO 11070: 1998, Sect. 4.4 & Annex B
	Radiodetectability	ISO 11070: 1998, Sect. 4.5 / ASTM F640-12
	Liquid leakage through sheath	ISO 11070:1998, Sect. 7.3 & Annex D
	Liquid leakage through valve	ISO 11070:1998, Sect. 7.4 & Annex E
	Sheath to housing joint strength	ISO 11070: 1998, Sect. 7.6
	Sheath tubing tensile strength	ISO 11070: 1998, Sect. 7.6
	Kink resistance	ISO 11070:1998, Annex A Section A.1
	Sheath side tube to housing joint strength	ISO 11070: 1998, Annex C *ISO 11070 does not require test on side tube Ref. for test method only
	3WSC to side tube joint strength	ISO 11070: 1998, Annex C *ISO 11070 does not require test on side tube Ref. for test method only
	Visual Inspection – housing color	Internal
	Penetration of Sheath, Dilator System in thin film, Sheath Tip Cracks	Internal
	Housing to cap joint strength	Internal
	Assembled side tube length	Internal
	Side tube burst	Internal
	Sheath housing to support joint strength	Internal
	Sheath Length	Internal
	Visual Inspection – Suture Eye	Internal
	Catheter insertion through valve	Internal
	Aspiration & injection through side tube	Internal
	External Lubricity	Internal
Particulate & Coating Integrity Testing Note: Test conducted using whole kit	FDA PTCA Guidance /USP788	

Table 5.5: Summary of Dilator Performance Testing

Component	Test # / Description	Standard
Dilator	Visual Inspection – Extraneous matter	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Process and surface defects	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Lubricant on external surfaces	ISO 11070: 1998, Sect. 4.3
	Corrosion Resistance	ISO 11070: 1998, Sect. 4.4 & Annex B
	Radiodetectability	ISO 11070: 1998, Sect. 4.5 ASTM F640-12
	Dilator tubing to hub joint strength	ISO 11070: 1998, Sect. 9.3.3 & Annex C
	Gauge Luer Taper	ISO 594-1:1986, Sect. 5.1
	Liquid Leakage from fitting assembly under pressure	ISO 594-2: 1998, Sect. 5.2
	Air leakage into the fitting assembly during aspiration	ISO 594-2: 1998, Sect. 5.3
	Separation force of fitting assembly	ISO 594-2:1998, Sect. 5.4
	Unscrewing torque of fitting assembly	ISO 594-2:1998, Sect. 5.5
	Ease of assembly	ISO 594-2:1998, Sect. 5.6
	Resistance to overriding	ISO 594-2: 1998, Sect. 5.7
	Stress cracking	ISO 594-2: 1998, Sect. 5.8
	Visual Inspection – hub color	Internal
	Dilator hub to sheath housing fitting strength	Internal
	Dilator OD at Sheath Tip interface & shaft OD; Sheath tip ID	Internal
	Dilator Length	Internal
	Dilator tip ID	Internal
	Penetration of Dilator System in thin film	Internal
Pass wire through dilator to check for blockage	Internal	

Table 5.6: Summary of Guide Wire Performance Testing

Guide Wires	Visual Inspection – Extraneous matter	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Process and surface defects	ISO 11070: 1998, Sec. 4.3
	Visual Inspection – Lubricant on external surfaces	ISO 11070: 1998, Sec. 4.3
	Corrosion Resistance	ISO 11070: 1998, Sect. 4.4 & Annex B
	Radiodetectability	ISO 11070: 1998, Sec. 4.5 ASTM F640-12
	Test for fracture of guide wires	ISO 11070: 1998, Annex F
	Test for resistance of guide wires to damage by flexing	ISO 11070: 1998, Annex G
	Guide Wire Tensile	ISO 11070: 1998, Annex H
	Guide Wire OD	Internal
	Guide Wire length	Internal
	Tip buckling (Tip butt resistance) test	Internal
	Insertion against flashback	Internal
	Removal through standard 21G needle (Nitinol Wire only)	Internal

Table 5.7: Summary of Entry Needles Performance Testing

Entry Needles (including Surflo (SR) I.V. Catheter)	Visual Inspection – Extraneous matter	ISO 11070: 1998, Sect. 4.3
	Visual Inspection – Process and surface defects	ISO 11070: 1998, Sec. 4.3
	Visual Inspection – Lubricant on external surfaces	ISO 11070: 1998, Sec. 4.3
	Corrosion Resistance	ISO 11070: 1998, Sect. 4.4 & Annex B
	Radiodetectability	ISO 11070: 1998, Sec. 4.5 ASTM F640-12
	Visual Inspection – Needle Point	ISO11070:1998, Section 5.3
	Distance from heel of needle to catheter tip (Surflo Needle test only)	ISO 11070: 1998, section 6.2
	Catheter to hub joint strength (Surflo Catheter test only)	ISO 11070:1998, Annex C
	Needle to hub joint strength	ISO/ FDIS 11070: 2014, Annex I
	Gauge Luer Taper	ISO 594-1:1998, Sect. 5.1
	Liquid Leakage from fitting assembly under pressure	ISO 594-2: 1998, Sect. 5.2 ISO 594-1: 1986, Sect. 5.2 for SR Needles only
	Air leakage into the fitting assembly during aspiration	ISO 594-2: 1998, Sect. 5.3 ISO 594-1: 1986, Sect. 5.3 for SR Needles only
	Separation force of fitting assembly	ISO 594-2: 1998, Sect. 5.4 ISO 594-1: 1986, Sect. 5.4 for SR Needles only
	Unscrewing torque of fitting assembly (SR needles not included)	ISO 594-2:1998, Sect. 5.5
	Ease of assembly (SR needles not included)	ISO 594-2:1998, Sect. 5.6
	Resistance to overriding (SR needles not included)	ISO 594-2: 1998, Sect. 5.7
	Stress cracking	ISO 594-2: 1998, Sect. 5.8 ISO 594-1: 1986, Sect. 5.5 for SR Needles only
	Visual Inspection – hub color	ISO 6009:1992, Sect. 2
	Visual Inspection – SR Catheter hub	Internal
	Needle Length	Internal
	Needle bevel indicator position	Internal
	Needle bevel indicator Visibility	Internal
	Wire can pass through insertion device provided in kit (needles only)	Internal
Needle I.D.	Internal	
Needle Flashback	Internal	
Surflo I.V. Catheter Penetration	Internal	
Needle Penetration	Internal	

Table 5.8: Summary of Syringe Performance Testing

Syringe	Gauge Luer Taper	ISO 594-1:1986, Sect. 5.1
	Liquid Leakage from fitting assembly under pressure	ISO 594-1:1986, Sect. 5.2
	Air leakage into the fitting assembly during aspiration	ISO 594-1:1986, Sect. 5.3
	Separation force of fitting assembly	ISO 594-1:1986, Sect. 5.4
	Stress Cracking	ISO 594-1:1986, Sect. 5.5
	Barrel finger grips – Flash and Sharp edges	ISO 7886-1: 1993, Sect. 11.2
	Barrel finger grips - Rolling	ISO 7886-1: 1993, Sect.11.2
	Plunger length past finger grips	ISO 7886-1: 1993, Sect.12.1
	Fit of the piston in the barrel	ISO 7886-1: 1993, Sect. 12.2
	Piston/Plunger Assembly – One-Handed Design	ISO 7886-1: 1993, Sect. 12.1
	Separation force of fitting assembly	ISO 7886-1: 1993, Sect. 12.1
	Visual Inspection – lubricant inside of syringe barrel	ISO 7886-1: 1993, Sect. 8
	Visual Inspection – Glidesheath Access Kit w/ SR and Syringe	Internal

Table 5.9: Summary of 3-Way Stopcock Performance Testing

3-Way Stopcock	Gauge Luer Taper	ISO 594-1:1986, Sect. 5.1
	Liquid Leakage from fitting assembly under pressure	ISO 594-2:1998 Sec. 5.2
	Air leakage into the fitting assembly during aspiration	ISO 594-2:1998 Sec. 5.3
	Separation force of fitting assembly	ISO 594-2:1998 Sec. 5.4
	Unscrewing torque of fitting assembly	ISO 594-2:1998 Sec. 5.5
	Ease of assembly	ISO 594-2:1998 Sec. 5.6
	Resistance to overriding	ISO 594-2:1998 Sec. 5.7
	Stress cracking	ISO 594-2:1998 Sec. 5.8

The components tested met the predetermined acceptance criteria and results support a determination of substantial equivalence

Biocompatibility

The individual components of the Glidesheath were categorized according to the following:

- FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”
- EN ISO 10993-1.

Table 5.10 below provides the categorization of each of the Glidesheath components. Tests were then selected based upon these categorizations.

Table 5.10: The Glidesheath Blood/Body Contacting Components and Categorization

Device	Body Contact	Contact Duration
Introducer Sheath (Sheath and Dilator)	Externally communicating, Circulating Blood	Limited (<24 hours)
Guide Wires		
Plastic Jacketed Guide Wire	Externally communicating, Circulating Blood	Limited (<24 hours)
Stainless Steel Guide Wires (Straight and J-tip)	Externally communicating, Circulating Blood	Limited (<24 hours)
Nitinol Guide Wire	Externally communicating, Circulating Blood	Limited (<24 hours)
Entry Needles		
TRI Stainless Steel Entry Needle	Externally communicating, Circulating Blood	Limited (<24 hours)
TPC Stainless Steel Entry Needle	Externally communicating, Circulating Blood	Limited (<24 hours)
Surflo IV Catheter	Externally communicating, Circulating Blood	Limited (<24 hours)
Syringe		
Flushing Syringe	Externally communicating, Blood Path Indirect	Limited (<24 hours)

Table 5.11 provides a list of the Biocompatibility test conducted on the proposed TMC Glidesheath introducer (sheath & dilator) and accessories.

Table 5.11: Summary of ISO 10993 Biocompatibility Testing

Non-aged, whole device (finished, sterile)
Cytotoxicity
Hemocompatibility (Hemolysis and Thrombogenicity)
Sensitization
Intracutaneous reactivity (acute)
Systemic toxicity (acute)
Pyrogenicity
Physicochemical
Accelerated-aged (12m), whole device (finished, sterile)
Cytotoxicity
Hemolysis
Physicochemical

In addition to testing defined above, Extractables and Acidity/Alkalinity testing was performed on the needles per ISO 7864: 1993, Sterile hypodermic needles for single use (Annex A). All tests results met requirements.

All of the blood/body contacting materials present in the proposed TMC Glidesheath, including all accessories, have been tested for biocompatibility. The testing, conducted on the whole devices (finished, sterile), demonstrate that all test articles of the proposed TMC Glidesheath, including accessories, are biocompatible; furthermore, the screening tests demonstrate that biocompatibility of the device is maintained throughout its shelf life.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with EN ISO 11135: 2014, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*.

The device is sterilized to provide a Sterility Assurance Level (SAL) of 10⁻⁶ using the overkill half cycle approach.

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 proposed Glidesheath manufactured by Terumo Medical Corporation, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device(s):

K082644 – Glidesheath manufactured by Terumo Corporation