



December 18, 2025

Terumo Medical Products (Hangzhou) Co., Ltd.
Kimberly Jacob-Paredes
Regulatory Affairs Specialist
M4-9-5, Hangzhou Economic & Technological Development Zone
Hangzhou, 310018
China

Re: K252402

Trade/Device Name: Midline 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 Kimberly Jacob-Paredes:

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)

K252402

Device Name

Midline Catheter

Indications for Use (Describe)

The Midline Catheter is indicated for insertion into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. It may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The Midline Catheter is suitable for use with power injectors.

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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Midline Catheter

510(k) Summary

510(k) SUMMARY – K252402

SUBMITTER INFORMATION

Contact Details: *Owner/Operator*

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Date prepared: December 18th, 2025

SUBJECT DEVICE

Trade Name: Midline 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



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Midline Catheter
510(k) Summary

PREDICATE DEVICE

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

Predicate Device: K162377-PowerGlide Pro™ Midline Catheter

Manufacturer: C. R. Bard, Inc.
Regulation: 21 CFR 880.5200
Product Code: FOZ
Classification: Class II

DEVICE DESCRIPTION

The Midline Catheter is a peripherally inserted catheter composed of a radiopaque polyurethane catheter, a catheter slider, a catheter hub, needle hub, and 3D-Shin™ needle featuring an engineered three-dimensional geometry of the needle tip, with a passive safety mechanism. After observing the blood return, the 3D-Shin™ needle is withdrawn, and the needle tip is fully covered by the safety mechanism, reducing the risk of accidental needlestick injury.

Design/Construction

The subject device and the predicate device PowerGlide Pro™ Midline Catheter (K162377) have similar construction, except for the Guidewire component and the Tip configuration.



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Materials

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

Table 1: List of Materials

No.	Name of Component	Raw Material
1**	Catheter	Polyurethane
2**	Catheter Tip	Polyurethane
3*	Inner Needle	Stainless steel
4*	Rivet pin	Stainless steel
5*	Hemostasis valve	Isoprene rubber
6	Catheter protector	Polypropylene
7	Grip	Polycarbonate
8	Needle hub	Polycarbonate
9*	Catheter hub	Polypropylene
10	Catheter slider	Polypropylene
11*	Plug	Polycarbonate
12*	Plug Holder	Polypropylene
13	Safety shield	Polycarbonate

* Blood Path, Indirect, **Circulating Blood



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Midline Catheter

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Specifications

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

Table 2: Midline Catheter Specifications

Product code	Lumen	Needle type	Catheter gauge	Catheter length	Safety cover	Color of catheter hub
MCS1810D00F	Single lumen	3D needle	18G	100mm	Type 1	Green
MCS1808D00F			18G	80mm	Type 2	
MCS2010D00F			20G	100mm	Type 1	Pink
MCS2008D00F			20G	80mm	Type 2	
MCS2208D00F			22G	80mm	Type 2	

INDICATIONS FOR USE

The Midline Catheter is indicated for insertion into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. It may be used for any patient population, with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.

The Midline Catheter is suitable for use with power injectors.

TECHNOLOGICAL CHARACTERISTICS

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



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Midline Catheter

510(k) Summary

Table 3: Comparison of Technological Characteristics

Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
<i>Indications for Use</i>	The Midline Catheter is indicated for insertion into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. It may be used for any patient population, with consideration given to the adequacy of vascular anatomy and appropriateness of the procedure. The Midline Catheter is suitable for use with power injectors	The PowerGlide Pro™ Midline Catheter is inserted into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide Pro™ Midline Catheter is suitable for use with power injectors.	Same
<i>Operation Principle</i>	Manual	Same	Same
<i>Design / Construction</i>	<ul style="list-style-type: none"> • Catheter assembly (catheter, catheter slide, catheter hub, inner needle, needle hub) In accordance with ISO 10555-1	<ul style="list-style-type: none"> • Catheter assembly (catheter and hub, introducer needle, needle hub, and Guidewire) In accordance with ISO 10555-1	The Midline Catheter is not intended for use with a guidewire. To address this concern, Terumo conducted a Tip Flexural Fatigue test to simulate cyclic kinking



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
			and evaluate burst pressure performance. In this test, the catheter tip underwent 30 cycles of bending and releasing, followed by a burst pressure test in accordance with ISO 10555-1:2023. The results demonstrated that the product remained intact throughout the testing process. Based on these findings, Terumo believes that the Midline Catheter does not introduce any new safety or effectiveness concerns, even when used without a guidewire.
Materials	<ul style="list-style-type: none"> • **Catheter – Polyurethane • *Catheter Hub – Polypropylene • *Inner Needle – Stainless Steel • **Catheter Tip – Polyurethane • Catheter Slider - 	<ul style="list-style-type: none"> • Catheter – Polyurethane • Catheter Hub – Isoplast Polyurethane • Needle – Stainless Steel • Catheter Tip – Isoplast Polyurethane • Guidewire - Nitinol 	Although the materials differ, Terumo has conducted chemical characterization and biocompatibility tests on the Midline Catheter, and the results confirm that the materials do not raise different questions



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
	Polypropylene		of safety or effectiveness compared to the predicate.
Materials	<ul style="list-style-type: none"> • Guidewire - Not Applicable • Needle Hub - Polycarbonate • *Rivet Pin - Stainless Steel • *Hemostasis valve - Polyisoprene • Catheter Protector - Polypropylene • Grip - Polycarbonate • Catheter Slider - Polypropylene • *Plug - Polycarbonate • *Plug Holder - Polypropylene • Safety Shield - Polycarbonate 	<ul style="list-style-type: none"> • Guidewire Nitinol • Needle Hub - Information not publicly known • Rivet Pin - Not Applicable • Hemostasis Valve - Not Applicable • Catheter Protector - Information not publicly known • Grip - Information not publicly known • Catheter Slider - Information not publicly known • Plug - Not Applicable • Plug holder - Not Applicable • Safety Shield - Information not publicly known 	<p>Rivet Pin: The rivet pin serves as a mechanical function by securely connecting the catheter to the catheter hub. This connection is critical to prevent the catheter from detaching during use. Risks associated with the rivet pin have been addressed through biocompatibility testing and MRI safety evaluation. Additionally, per ISO 10555-1, tensile strength testing was conducted on the catheter and the catheter hub connection for both the Midline Catheter and the predicate device. Results confirmed equivalent</p>



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
			<p>mechanical performance.</p> <p>Hemostasis Valve and Plug/Plug Holder: The hemostasis valve is designed to prevent blood leakage during catheter insertion. When a male Luer is connected, it pushes the plug forward, which in turn opens the valve to establish a fluid path. The plug and plug holder are components that support this function. Biocompatibility testing has been completed for all materials, and no new risks were identified. The valve and plug do not introduce new safety or effectiveness concerns compared to the predicate.</p>



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Midline Catheter

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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
			<p>Needle and Needle Hub: Tensile strength testing was conducted per in-house standards based on the predicate's performance. Testing was conducted on the needle and the needle hub for both the Midline Catheter and the predicate device. Results demonstrated equivalent mechanical performance.</p> <p>Catheter Slider and Grip: Slider resistance testing was conducted per in-house standards based on the predicate's performance. The catheter slider and grip are integrated components on both the Midline catheter and the predicate device.</p>



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
			<p>Protector Fitting Strength: Fitting strength testing of the protector was conducted per in-house standards based on the predicate's performance. Results confirmed equivalent retention and reliability.</p> <p>Safety Shield Performance: Per ISO 23908, the Safety shield performance was validated for both the Midline Catheter and the predicate device. The test results demonstrated equivalent protection against needlestick injury.</p>
Package Specifications	<ul style="list-style-type: none"> • Unit Box • Shelf box • Shipping carton • Patient Label 	<ul style="list-style-type: none"> • Unit Box • Shelf box • Shipping carton • Patient Label 	Same



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
	18G, 20G, 22G	18G, 20G, 22G	Same
<i>Sterilization</i>	EO (validated in accordance with ISO 11135 to achieve SAL 10 ⁻⁶)	Provided Sterile (EO)	Same
<i>Shelf life</i>	3 Years	Not Publicly Available	Although the predicate device does not publicly disclose its shelf life duration, the proposed 3 year shelf life for the Midline Catheter does not raise new questions of safety or effectiveness based on testing conducted in accordance with ASTM F1980 and ISO 10993. These studies confirmed that the device maintains its physical integrity, sterility, and functional performance throughout the proposed shelf life.



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Device Characteristic	Subject Device Specifications: Midline Catheter	Predicate Device Specifications: PowerGlide Pro™ Midline Catheter, K162377	Same/Different Assessment
<i>MRI Safety</i>	MR Conditional	Not Applicable	Although the predicate device does not claim MRI compatibility, the Midline Catheter has the MR conditional symbol on the label, which is supported by a comprehensive MR safety test in accordance with ASTM F2052-21, ASTM F2213-2017, and ASTM F2119-07(2013). These tests confirmed that the device meets the criteria for MR Conditional.
<i>Power Injection Maximum Flow Rate</i>	18G = 7mL/sec 20G = 5mL/sec 22G = 2mL/sec	18G = 7mL/sec 20G = 5mL/sec 22G = 2mL/sec	Same

* Blood Path, Indirect, **Circulating Blood



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Midline Catheter

510(k) Summary

NON-CLINICAL TESTS

Performance

Performance testing was conducted to verify the safety and effectiveness of the Midline Catheter. This device is intended for short-term use (less than 30 days) for blood sampling or intravenous fluid administration. It is suitable for all patient populations, with consideration given to the adequacy of vascular anatomy and appropriateness of the procedure. The Midline catheter is compatible with power injectors throughout its shelf life. Testing was performed to confirm compliance with relevant internal and external standards, demonstrate MR Conditional status, and establish substantial equivalence to the predicate device. Performance tests were carried out on both non-aged and accelerated-aged samples. **Table 4** below outlines the specific performance tests conducted on the Midline Catheter.

Table 4: Summary of Performance Tests

Test Item
Activation of Safety Mechanism
Safety Cover Tensile Strength
Needle Tip Exposure in Safe Mode
Catheter Tip Adhesion Break Force
Swelling Outer Diameter (OD)
Catheter Collapse
Tip Location During and After Power Injection
Tip Flexural Fatigue (Cyclic Kinking and Burst Test)
Tip Separation Force
Simulated Clinical Use
MRI Compatibility Test
Radiopacity Test
Particle Contamination



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Midline Catheter

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MRI Compatibility Testing

MRI compatibility testing was conducted on the finished Midline Catheter, excluding the needle component. To remove the needle, the device’s safety mechanism must be activated; therefore, only the catheter and catheter hub were included in the evaluation. Testing was performed in accordance with the recommendations outlined in the FDA Guidance Document for Industry and FDA Staff, “*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.*” The objective was to determine MR Conditional safety information for the device. **Table 5** below summarizes the MRI tests performed on the Midline 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 confirmed that all predetermined acceptance criteria were met. The results support that the Midline Catheter is suitable for clinical use throughout its labeled shelf life and meets the criteria for **MR Conditional**.



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Midline Catheter

510(k) Summary

Biocompatibility Classification

In accordance with ISO 10993-1, the Midline Catheter is classified as an Externally Communicating Device, Circulating Blood, Prolonged Exposure (24 hours to 30 days).

Chemical Characterization

Chemical Characterization was conducted on the finished sterilized device in accordance with ISO 10993-18: 2020. Testing results demonstrate that no extractables at concentrations higher than the toxicological screening limit (TSL) were detected.

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** below provides a list of biocompatibility testing conducted on the Midline Catheter.



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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
Sensitization	ISO 10993-10:2021
Irritation or Intracutaneous Reactivity	ISO 10993-23:2021
Acute System Toxicity	ISO 10993-11:2017
Subacute Toxicity	ISO 10993-11:2017
Complement Activation	ISO 10993-4:2017
Pyrogenicity	USP, General Chapter <151>
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 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 Midline Catheter is sterilized to provide a Sterility Assurance Level (SAL) of 10⁻⁶.



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510(k) Summary

CLINICAL TESTS

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

CONCLUSION

In summary, the Midline Catheter, which is the subject of this Traditional 510(k) submission, is substantially equivalent in its intended use, technological characteristics, materials, and performance to the PowerGlide Pro™ Midline Catheter (K162377), manufactured by C. R. Bard, Inc.