



December 3, 2025

Bend It Technologies Ltd.
% Sheila Hemeon-Heyer, JD, RAC
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K252213

Trade/Device Name: Bendit17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 6, 2025
Received: November 6, 2025

Dear Sheila Hemeon-Heyer:

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,

NAIRA MURADYAN -S

Naira Muradyan, Ph.D.

Assistant Director

DHT5A: Division of Neurosurgical,

Neurointerventional, and

Neurodiagnostic Devices

OHT5: Office of Neurological and

Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K252213

Device Name

Bendit17 Microcatheter

Indications for Use (Describe)

The Bendit17 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices.

Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

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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510(k) Summary K252213

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

- A. Submitter:** Bend It Technologies Ltd.
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Contact: Simona Beilin-Nissan
Title: Vice President Clinical and Regulatory Affairs
Tel #: +972 3 6747377
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- B. Date Prepared:** December 2, 2025
- C. Device Name and Classification Information:**
- | | |
|-------------------------|--|
| Trade Name: | Bendit®17 Microcatheter |
| Common/Usual Name: | Steerable microcatheter |
| Classification Name: | Catheter, percutaneous, neurovasculature |
| Regulation: | 21 CFR 870.1250 |
| Product Code: | QJP |
| Secondary Product Code: | DQY |
| Review Panel: | Neurology |
| Regulatory Class: | Class II |
- D. Predicate Device:** Bendit®21 Microcatheter, K203842
Reference Devices: VIA 17 Microcatheter, K192135
Headway 17 Advanced Microcatheter, K101542

E. Device Description:

The Bendit®17 Microcatheter is a steerable microcatheter with a steerable distal tip. The tip's deflection is controlled using the Steering Slider on the proximal Steering Handle. The tip can be rotated bi-directionally while deflected by turning the Torque Knob on the Steering Handle.

The total working length of the Bendit®17 Microcatheter is 151 cm. It is comprised of two Nitinol hypo tubes that are connected at their distal ends, with proprietary laser-cut patterns along the 38 cm distal section. The laser cuts give the Bendit®17 Microcatheter its flexibility while maintaining the Nitinol torsional rigidity for a high torque response. The distal 10 mm section is steerable and includes two radiopaque markers, one at the tip and a radiopaque band located 30 mm proximally from the tip. The distal portion of the catheter shaft (100 cm) is covered with a hydrophilic coating.

Sliding the Steering Slider forward moves the hypo tubes so that the distal tip deflects. When the Steering Slider is released, the tip shape is locked. The Bendit®17 lumen can accommodate

compatible guidewires (≤ 0.014 "). A standard Luer lock port for attachment of accessories is located at the proximal end of the Steering Handle.

The Bendit®17 is compatible with the following types of therapeutic devices:

- Embolization particles with maximum particle size of 400 μm
- Coils with maximum coil wire size of 0.014"
- Stents/stent retrievers/intrasaccular flow disruption devices compatible with microcatheters with inner diameter of 0.017"

F. Indications for Use Statement:

The Bendit®17 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices.

Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

G. Technical Comparison Table

The table below provides a technological comparison between the Bendit®17 Microcatheter, the predicate device, and the reference devices. The differences between the Bendit®17 Microcatheter, the predicate device, and reference devices and why these differences do not impact substantial equivalence are discussed following the table.

Table 1. Substantial Equivalence Comparison Table

	Subject Device Bendit®17 Microcatheter (K252213)	Predicate Device Bendit®21 Microcatheter (K203842)	Reference Device VIA 17 Microcatheter (K192135)	Reference Device Headway®17 Advanced Microcatheter (K101542)	Comparison
Manufacturer	Bend It Technologies Ltd.	Bend It Technologies Ltd.	MicroVention, Inc.	MicroVention, Inc.	Same as predicate.
Regulation	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	Same
Class	Class II	Class II	Class II	Class II	Same
Product Code	QJP, DQY	QJP, DQY	DQY, KRA	DQY	Same as predicate.
Indications for Use	The Bendit17 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.	The Bendit21 Microcatheter is intended for use in accessing target locations in the peripheral, coronary, and neuro vasculature and can be used to deliver both diagnostic agents, such as contrast media, and therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.	The VIA Microcatheter is intended for the introduction of interventional devices (such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.	The Headway 17 Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	Same as predicate.

	Subject Device Bendit®17 Microcatheter (K252213)	Predicate Device Bendit®21 Microcatheter (K203842)	Reference Device VIA 17 Microcatheter (K192135)	Reference Device Headway®17 Advanced Microcatheter (K101542)	Comparison
Description	A single lumen catheter designed to be introduced either with or without a steerable guidewire to access small, torturous vasculature. The bendable proximal section transitions to a flexible, steerable distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	A single lumen catheter designed to be introduced either with or without a steerable guidewire to access small, torturous vasculature. The bendable proximal section transitions to a flexible, steerable distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	A single lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The tip configuration is straight or preshaped to 45° or 90°. Dual radiopaque marker bands at the distal end facilitate visualization of the tip using fluoroscopic techniques. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	A single lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The semi-rigid proximal section transitions to a flexible distal tip, which is steam shapeable by the physician prior to use. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.	Same as predicate.
Handle	Steering slider which enables control of deflection. Torque knob which enables micro-torquing.	Steering slider which enables control of deflection. Torque knob which enables micro-torquing.	Standard fixed Luer hub (non-steerable)	Standard fixed Luer hub (non-steerable)	Same as predicate.

	Subject Device Bendit®17 Microcatheter (K252213)	Predicate Device Bendit®21 Microcatheter (K203842)	Reference Device VIA 17 Microcatheter (K192135)	Reference Device Headway®17 Advanced Microcatheter (K101542)	Comparison
Catheter Body	Outer layer: Pebax with hydrophilic coating on distal 100cm. Inner layer: PTFE. Between outer and inner layer is a coaxial tube configuration comprised of two Nitinol tubes.	Outer layer: Pebax with hydrophilic coating on distal 75cm. Inner layer: PTFE. Between outer and inner layer is a coaxial tube configuration comprised of two Nitinol tubes.	Outer layer of Pebax and Vestamid with hydrophilic coating on distal 100cm. Inner layer: PTFE. Between outer and inner layer is stainless steel braid and coil.	Outer layer of Pebax and Grilamid with hydrophilic coating on distal 100cm. Inner layer: PTFE. Between outer and inner layer is stainless steel braid and coil.	Same as predicate except the length of hydrophilic coating is 25cm longer which is the same as on reference devices.
Deflecting Section	Bending distal section 10mm. Tip deflection inner radius 2mm.	Bending distal section 12mm. Tip deflection inner radius 3mm.	Option of preshaped or steam shapeable	Steam shapeable by physician prior to use	Same as predicate except slightly smaller dimensions.
Flexible Shaft	Tapered flexibility from proximal to distal.	Tapered flexibility from proximal to distal.	Flexible catheter shaft	Flexible catheter shaft	Same as predicate.
Catheter OD	2.7 Fr 0.9mm 0.035"	3.1 Fr 1.03mm 0.041"	2.2 Fr 0.74mm 0.029"	1.7-2.4 Fr 0.56 – 0.79mm 0.022 - 0.031"	Between predicate and reference devices.
Catheter ID	0.017" 0.43mm	0.021" 0.53mm	0.0175" 0.44mm	0.017" 0.43mm	Smaller than predicate. Same as reference devices.
Effective Length	151cm	157cm	154cm	150cm	Between predicate and reference devices.

	Subject Device Bendit®17 Microcatheter (K252213)	Predicate Device Bendit®21 Microcatheter (K203842)	Reference Device VIA 17 Microcatheter (K192135)	Reference Device Headway®17 Advanced Microcatheter (K101542)	Comparison
Radiopaque Marker	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium	Same
Radiopaque Tip	Tungsten	Tungsten	Platinum/Iridium	Platinum/Iridium	Same as predicate.
Method of Supply	Sterile, single-use, disposable	Sterile, single-use, disposable	Sterile, single-use, disposable	Sterile, single-use, disposable	Same

H. Discussion of Differences

The predicate device is the Bendit®21 Microcatheter (K203842). The main differences between the Bendit®17 Microcatheter and the predicate Bendit®21 Microcatheter device are the dimensions, with the Bendit®17 Microcatheter having reduced ID, OD, and effective length in order to be consistent with these specifications for the same sized microcatheters offered by competitors (the reference devices VIA 17 and the Headway 17 Advanced Microcatheters). The reduced catheter size does not raise any new questions of safety or effectiveness. The Bendit®17 Microcatheter is indicated for the same use and is operated in the same way as the predicate Bendit®21 Microcatheter.

The increased length of hydrophilic coating on the Bendit®17 compared to the Bendit®21 also does not present any new risks or increased risk level and has no impact on the device safety and effectiveness as this specification is now consistent with that of the same sized reference microcatheters. Testing presented in this 510(k) Summary confirms that this change has not increased the amount of recovered particulate matter (see below).

Other minor changes are intended to facilitate the user experience with no new risks or risk level changes that affect device safety or effectiveness.

I. Testing to Support Substantial Equivalence

In Vitro Bench Testing

Bench performance testing of the Bendit®17 Microcatheter was conducted in accordance with ISO 10555-1:2023 “Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements”, where applicable, and internal test methods as summarized below in **Table 2**. In addition, testing of the device Luer was conducted in accordance with ISO 80369-7:2021, “Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications,” and ISO 80369-20:2015, “Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods.” All tests were conducted on both as manufactured (t=0) and accelerated aged (equivalent to t=18 months) devices except where noted (see asterisks). Sample sizes for all tests were established to demonstrate 95%/90% confidence/reliability in the test results.

Table 2. Summary of Performance Testing

Test Name	Test Method Summary	Results
Visual and Dimensional Inspections	Visual inspections for extraneous matter, surface defects, sharp edges. Measurements of device dimensions, such as angles, lengths, diameters.	Pass. No visual evidence of foreign matter, surface defects or sharp edges. All measurements met the pre- defined acceptance criteria.
Kink Resistance	Microcatheter samples are advanced and bent around a challenging radius curve jig, without evidence of kink.	Pass. The microcatheter demonstrated kink resistance in accordance with the test acceptance criteria.
Simulated Use, including: • Deflection • Pushability • Retractability • Torqueability	Microcatheter samples are navigated to anatomical locations within a neurovascular tortuous model and evaluated for deflection, pushability, retractability, torqueability and damage post testing. Measurements of forces at the proximal end that are required to cause movement at the distal end.	Pass. All samples were successfully navigated through the tortuous model without damage and met the pre-defined acceptance criteria for forces.
Peak Tensile Strength	Measurement of the forces at each microcatheter junction needed to separate the microcatheter into two or more pieces.	Pass. Tensile force to break for all samples for all junctions met the pre-defined acceptance criteria.
Air Leakage	Included generating a reduced pressure to the microcatheter, and verifying the device is air leak proof.	Pass. No evidence of air leakage.
Liquid Leakage	Applying liquid pressure to the microcatheter and verifying the device is liquid leak proof.	Pass. No evidence of liquid leakage.
Priming Volume*	Measurement of the microcatheter priming volume and verification that it does not exceed a predefined volume.	Pass. Priming volume for all samples met the pre-defined acceptance criteria.
Fatigue (Tip Deflection and Tip Rotation Cycles)	Testing for tip deflection and tip rotation both in a tortuous simulated pathway.	Pass. All samples exceeded the pre-defined number of tip deflection and tip rotation cycles without damage.
Torque to Failure	Measurement of the number of rotation cycles required to cause microcatheter breakage/kink when the tip is restrained, in a tortuous simulated pathway.	Pass. All samples exceeded the minimum number of cycles set by the test acceptance criterion before failure.
Torque Strength (Handle to Shaft)	Measurement of torque strength required to cause microcatheter breakage/kink between handle to shaft.	Pass. All samples met the predefined acceptance criteria.
Torque Transmission	Measurement of proximal-to-distal torque response and rotational ratio, in tortuous anatomy.	Pass. All measurements met the pre-defined acceptance criteria.
Flow Rate*	Measurement of the microcatheter flow rate through a constant level tank based on amount of water collected during a pre-defined time period.	Pass. All measurements met the pre-defined acceptance criteria.

Test Name	Test Method Summary	Results
Pressure Injection Flow Rate	Evaluation of the ability of the microcatheter to withstand high dynamic pressures and characterization of flow rate.	Pass. All samples withstood the applied injection pressures under the conditions of the testing without damage.
Burst Pressure	Applying gradually elevated static pressure and verifying the device can withstand the highest predefined pressure.	Pass. All samples withstood the applied static pressure under the conditions of the testing without damage.
Interventional Device Delivery Force	Assessment of the compatibility of the microcatheter to deliver representative therapeutic device in an anatomical tortuous model, in terms of delivery forces and visible damage.	Pass. All samples were able to deliver all therapeutic devices used in the testing using acceptable delivery force and without any visible damage to the microcatheter.
Tip Deflection Force	Measurement of the tip deflection force while in tortuous anatomical model.	Pass. All measurements met the predefined acceptance criteria.
Tip Buckling Forces	Characterization of the forces that induce buckling deformation at different distances from the distal tip.	Pass. Tip flexibility was comparable to the predicate and reference device.
Particulate Characterization	The light obscuration particle counting method of USP <788> and in accordance with the recommendations of AAMI TIR42:2021 was used to measure the total number of particulates generated during simulated use in a tortuous model after passage of a representative worst-case therapeutic device within the inner lumen.	Pass. Particulate generation was acceptable and comparable to the predicate device.
Coating Integrity	Visual inspection of microcatheter surface to identify the location and size of any coating voids before and after simulated use.	Pass. All samples demonstrated acceptable coating integrity before and after simulated use.
Coating Length	Measurement of microcatheter coating length.	Pass. The coating length for all samples met the pre-defined acceptance criteria.
Luer testing According to Standard	Testing according to ISO 80369-7:2021 and ISO 80369-20:2015.	Pass. All samples met the pre-defined acceptance criteria.
Compatibility with Interventional Devices (Usability)**	Compatibility with interventional devices in a tortuous simulated model (e.g., neurovascular stents, stent retrievers, coils, and intrasaccular flow disruption devices).	Pass. All samples met the pre-defined acceptance criteria.
Radiopacity***	Assessment of fluoroscopic visibility of the microcatheter shaft, proximal marker and tip.	Pass. All samples met the pre-defined acceptance criteria.

*Tests conducted only on “as manufactured” (t=0) devices because the attributes measured by these tests were determined to not be affected by aging (only priming volume and flow rate).

**Test conducted as part of the usability study.

***Test conducted as part of the usability study and animal study.

Animal Testing

The safety and performance of the Bendit®17 Microcatheter were evaluated in comparison to a reference device VIA 17 Microcatheter using a porcine vascular model. The animal study was conducted in compliance with Good Laboratory Practice (GLP) regulations (21 CFR Part 58). The Bendit®17 features an articulating tip adjustable from neutral to 180 degrees at the operator's discretion, whereas the VIA 17 used in the study incorporated a fixed 90-degree pre-shaped tip.

Both devices were tested in the same animal (n=4), with the Bendit®17 Microcatheter and VIA 17 pre-shaped 90° Microcatheter used on opposite sides to access target locations within the renal arteries and extracranial vessels, selected to mimic the anatomical challenges encountered in distal intracranial neurovascular procedures.

To simulate worst-case clinical conditions, multiple passes (three per vessel) were performed with each device through the same vascular pathway to the same target location. For the Bendit®17 Microcatheter, tip articulation and torque were maximally exercised within the target vessel.

Animals were terminated at 2 or 29 days post-procedure to assess both acute and subacute tissue response. Device safety was evaluated based on each animal's clinical condition, vessel patency and both macroscopic and histopathological assessments of the target vessels and downstream organs. Usability was assessed using pre-defined criteria, including visibility, trackability, pushability, torqueability, retraction, and ease of use.

Test results demonstrate the substantial equivalence of the Bendit®17 Microcatheter to the predicate VIA 17 pre-shaped 90° Microcatheter.

Biocompatibility

The Bendit®17 Microcatheter is an externally communicating device with limited duration (≤24 hours) of contact with circulating blood. The tests for devices in this patient contact category, shown in **Table 3**, were conducted in compliance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," and 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"."

Table 3. Summary of Biocompatibility Testing

Test Standard and Study Name	Test Method Summary	Results
ISO 10993-5 Cytotoxicity Study Using the ISO Elution Method	Cell viability was evaluated. If viability is reduced to <50%, the device has a cytotoxic potential.	Non-cytotoxic

Test Standard and Study Name	Test Method Summary	Results
ISO 10993-10 ISO Guinea Pig Maximization Sensitization Test	Animals tested with the test extract should show no evidence of delayed dermal contact sensitization.	Non-sensitizer
ISO 10993-23 ISO Intracutaneous Study in Rabbits	Animals injected with the test extract should have a final test sample score of 1.0 or less.	Non-irritant
ISO 10993-11 ISO Acute Systemic Toxicity Study in Mice	No animals injected with test article show a significantly greater biological reaction than the animals treated with the control article.	No acute systemic toxicity
ISO 10993-11 USP <151>, Pyrogen Test USP Rabbit Pyrogen Study	No single animal tested with test extract should exhibit increase of body temperature by more than 0.5°C.	Non-pyrogenic
ISO 10993-4, ASTM F756 ASTM Hemolysis Study	Mean hemolytic index for the direct contact and indirect contact should be < 2%.	Non-hemolytic
ISO 10993-4 SC5b-9 Complement Activation Assay	The SC5b-9 concentration of the test sample shall not be statistically higher than both the activated normal human serum and negative controls or be comparable to predicate control.	Non-activator of the complement system
ISO 10993-4 Thrombogenicity GLP Non-Anticoagulated Venous Implant (NAVI) Study of Thrombosis in Canine Model	Minimal thrombus formation on the subject device test article and results are comparable between the subject and control devices.	Non-thrombogenic

Sterilization Validation

Ethylene oxide (EO) sterilization was validated to a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle, overkill method per ISO 11135:2014/Amd 1:2018, "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices."

Bacterial endotoxin testing conducted using the LAL Test per USP 40-NF35:2017 <85> "Bacterial Endotoxins Test" confirmed endotoxin levels below 2.15 endotoxin units (EU)/device. EO and Ethylene Chlorohydrin residuals were evaluated according to ISO 10993-7:2008/Amd 1:2019

“Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals” and were below the limits specified in the standard.

Package and Shelf-Life Validation Testing

The packaging for the Bendit®17 Microcatheter is the same as for the predicate Bendit®21 Microcatheter. Device integrity testing following 18 months equivalent accelerated aging was completed to confirm the 18-month shelf life as presented in **Table 2**.

J. Conclusion

The Bendit®17 Microcatheter has the same indication for use and similar technological characteristics as the predicate device. The information and performance data presented in this 510(k) submission demonstrate that the subject device functions as intended and support a finding of substantial equivalence of the Bendit®17 Microcatheter to the predicate for use in the peripheral, coronary, and neuro vasculature.