August 22, 2019

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

Re: K190126
Trade/Device Name: Bendit2.7 Steerable Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: July 19, 2019
Received: July 22, 2019

Dear Ms. 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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190126

Device Name
Bendit2.7™ Steerable Microcatheter

Indications for Use *(Describe)*

The Bendit2.7 Steerable Microcatheter is intended for general intravascular use in the peripheral vasculature. The microcatheter can be used for the delivery of diagnostic, embolic, or therapeutic materials into the vasculature.

The Bendit2.7 is not intended to be used in intracranial or coronary vessels.

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.

510(k) Summary

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

A. Submitter:

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Amherst, MA 01004-2151
Contact: Sheila Hemeon-Heyer
Sheila@heyer-regulatory.com

B. Manufacturer/ 510(k) Applicant:

Bend It Technologies, Ltd
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C. Date Prepared: August 20, 2019

D. Device Name and Classification Information:

Trade Name:	Bendit2.7™ Steerable Microcatheter
Common/Usual Name:	Continuous Flush Catheter
Regulation:	21 CFR 870.1210
Product Code:	KRA
Review Panel:	Cardiovascular
Class:	II

E. Predicate Device:

Primary: SwiftNINJA, K161921
Reference: Direxion Torqueable Microcatheter, K132947

F. Summary Device Description:

The Bendit2.7™ 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 Bendit2.7™ is 130 cm. It is comprised of two Nitinol hypo tubes that are welded together at their distal ends, with proprietary laser-cut patterns along the 28-centimeter distal section. The laser cuts give the Bendit2.7™ its flexibility while maintaining the Nitinol torsional rigidity for a high torque response. The distal 12 mm

section is steerable and includes a radiopaque atraumatic tip. The shaft 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 Bendit2.7™ lumen can accommodate compatible guidewires (≤0.018"). A standard Luer lock port for attachment of accessories is located at the proximal end of the Steering Handle.

G. Indications for Use Statement:

The Bendit2.7™ Steerable Microcatheter is intended for general intravascular use in the peripheral vasculature. The microcatheter can be used for the delivery of diagnostic, embolic, or therapeutic materials into the vasculature.

The Bendit2.7™ is not intended to be used in intracranial or coronary vessels.

H. Technical Comparison with Predicate Devices

The table below provides a technological comparison between the proposed Bendit2.7™ and the predicate device. The similarities and differences between the proposed and predicate devices are discussed following the table.

	Proposed Device Bendit2.7™	**Primary Predicate SwiftNINJA**	**Reference Predicate Direxion**
Indications for Use	The Bendit2.7™Steerable Microcatheter is intended for general intravascular use, in the peripheral vasculature. The microcatheter can be used for the delivery of diagnostic, embolic, or therapeutic materials into the vasculature. The Bendit2.7 is not intended to be used in intracranial or coronary vessels.	The SwiftNINJA is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vasculature. The catheter should not be used in the cerebral vessels.	The Direxion Microcatheter is intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.
Catheter type	Steerable microcatheter	Steerable microcatheter	Distal tips are steam shapeable
Microcatheter Components	Catheter shaft, steerable deflecting tip, steering handle	Catheter shaft, steerable articulating tip, steering handle	Catheter shaft with luer on proximal end with rotating hemostatic valve (RHV) or Y-adapter, pre-loaded on guidewire, with a variety of tip shapes (Straight, Bern,

	Proposed Device Bendit2.7™	Primary Predicate SwiftNINJA	Reference Predicate Direxion
			Swan Neck, and J Shape)
Mode of operation	Catheter insertion and tip placement under imaging guidance. Tip deflection controlled using manual steering mechanism external to the body. Tip deflection achieved via two NiTi hypo tubes connected at the distal end of catheter with laser-cut patterns that provide tip flexibility. Material injection via syringe connection to luer at proximal end of catheter.	Catheter insertion and tip placement under imaging guidance. Tip articulation controlled using manual steering mechanism external to the body. Tip articulation achieved via two wires running along the inner walls of the catheter shaft from handle to tip. Material injection via syringe connection to luer at proximal end of catheter.	Catheter insertion and tip placement under imaging guidance. Tip are steam shapeable to aid in reaching the target. Material injection via syringe connection to luer at proximal end of catheter.
Catheter OD	2.7 Fr	2.9 Fr (proximal) / 2.4 Fr (distal)	2.7 Fr (proximal) / 2.5 Fr (distal)
Catheter ID	0.021"	0.021”	0.021”
Catheter shaft length	130 cm	125 cm	105, 130, 155 cm
Hydrophilic coating on shaft	Yes	Yes	Yes
Compatible guidewire	≤ 0.018"	≤ 0.018”	≤ 0.018”
# Lumens	Single	Single	Single
Fill volume	0.45 mL	0.49 mL	Unknown
Max injection pressure	1000 psi	1000 psi	1200 psi
Deflecting tip	Yes	Yes	No, steam shapeable
Max tip deflection angle	180° from neutral position in one direction	± 180° from neutral position	N/A, tips are steam shapeable
Max tip rotation	100° in both directions (clockwise and counter clockwise)	No mechanism for tip rotation separate from manually rotating catheter shaft.	No mechanism for tip rotation separate from manually rotating catheter shaft.
Radiopaque	Yes, radiopaque (tungsten) tip	Yes, two radiopaque (tungsten) markers in tip	Yes, one or two radiopaque markers in tip, depending on model
Steering mechanism	Slider used to deflect tip Knob used to rotate tip	Steering wheel used to deflect tip	N/A, not steerable
Steering lock mechanism	Yes	Yes	N/A

	Proposed Device Bendit2.7™	Primary Predicate SwiftNINJA	Reference Predicate Direxion
Max microsphere size	700 µm	700 µm	700 µm
Max coil size	0.018" (0.46 mm)	0.018" (0.46 mm)	Unknown
Biocompatibility	Complies with all required testing per FDA guidance for application of ISO 10993-1	Per 510(k) Summary, complies with all required testing per FDA guidance for application of ISO 10993-1	Assume compliance with ISO 10993-1
Use restriction	Single-use, disposable	Single-use, disposable	Single-use, disposable
Sterilization	Ethylene oxide, SAL 10^{-6}	Ethylene oxide, SAL 10^{-6}	Unknown

I. Discussion of Similarities and Differences

The Bendit2.7 has substantially equivalent indications for use as the predicate devices as all three devices are indicated for use in delivering diagnostic, embolic, or therapeutic materials into the peripheral vasculature.

The proposed and primary predicate devices are both steerable microcatheters consisting of a catheter shaft, steerable articulating tip, and steering mechanism in the handle. The mechanism of deflecting and rotating the tip are different between the two devices. However, testing provided in this 510(k) supports the substantial equivalence of the Bendit2.7 tip deflection mechanism to that of the predicate device.

The Bendit2.7 catheter is similar in size to both the primary and predicate devices, including OD, ID, fill volume, and catheter length. All devices are single lumen with a hydrophilic coating on the catheter shaft, radiopaque tips, and are intended for single patient use only.

The patient contacting materials of the Bendit2.7 have been shown to be biocompatible for short-term (≤ 24 hours) contact with circulating blood in compliance with the requirements of ISO 10993-1:2009.

J. Testing to Support Substantial Equivalence

In Vitro Bench Testing

The results of in vitro bench testing and animal testing provide comprehensive data to support the substantial equivalence of the Bendit2.7 Steerable Microcatheter. Testing was conducted in accordance with ISO 10555-1 Second edition 2013-06-15 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements (including Amendment 1:2017), where applicable.

Finished, sterilized, unaged and aged samples (minimum 6 months equivalent accelerated aged) of the Bendit2.7 Steerable Microcatheter were tested and shown to meet the design

inputs established for the device. The results of all tests met their pre-defined acceptance criteria. The following attributes were verified in bench testing:

Unaged (T0) Testing

- Visual inspections and dimensional verifications
- Tip tensile bond strength
- Liquid leakage
- Air leakage
- Power Injection (for Flowrate and Device Pressure)
- Coating integrity
- Particulates
- Simulated use testing in a tortuous model to evaluate performance handling / usability
- Package integrity testing

Aged (≥T6 months) Testing

- Visual inspections and dimensional verifications
- Flow rate
- Priming volume
- Tensile bond strength at main catheter junctions, including the catheter tip
- Torsional bond strength
- Liquid leakage
- Air leakage
- Kink resistance
- Power Injection (for Flowrate and Device Pressure)
- Coating integrity
- Particulates
- Corrosion
- Tip deflection cycles
- Tip rotation cycles
- Pushability and trackability
- Retraction
- Torqueability
- Simulated use testing in a tortuous model to evaluate performance handling / usability
- Package integrity testing

Animal Testing

The performance of the Bendit2.7 to reach target vessels and delivery diagnostic , embolic and therapeutic agents was evaluated in five different animal studies by four different interventional radiologists. Performance and handling characteristics of the Bendi2.7 were compared to the SwiftNINJA Steerable Microcatheter in one study and to the Direxion Torquable Microcatheter in a second study. Bendit2.7 was evaluated as equivalent when compared to both the SwiftNINJA and Direxion on all performance criteria including handling, tracking, and radiopacity/tip visualization.

Sterilization Validation

Ethylene oxide sterilization was validated to a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle, overkill method per ISO 11135:2014, 2nd edition, 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 well below the limit of the standard (<20.0 EU/Device), Sterilization residuals were evaluated according to ISO 10993-7:

Biocompatibility

The Bendit2.7 is externally communicating in short-term (<24 hours) contact with circulating blood. Biocompatibility of the patient contacting materials was confirmed in the following tests:

- Cytotoxity per ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization and Irritation per IO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Acute systemic toxicity per IO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Material-mediated pyrogenicity per USP 40-NF35:2017 <151> Pyrogen Test (USP Rabbit Test)
- Hemocompatibility per ISO 10993-4:2017 per Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood, including hemolysis per ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials; complement activation, and in vivo thrombogenicity

Package Testing after Aging and Simulated Transportation Testing

Samples of Bendit2.7 microcatheters that had been 2X EtO sterilized and aged in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices were then subjected to simulated environmental and shipping conditions and tested in accordance with ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems. Package integrity tests included the dye penetration test per ASTM F1929-15 and seal peel test per ASTM F88M/F88-15. Devices were subjected to integrity testing to confirm proper operation following aging and simulated distribution conditioning. All package and device integrity tests were passed.

K. Conclusion

The information and testing presented in this 510(k) demonstrate that the Bendit2.7™ Steerable Microcatheter is substantially equivalent to the SwiftNINJA Steerable Microcatheter for the delivery of diagnostic, embolic, or therapeutic materials into the peripheral vasculature.