June 25, 2020

Bend It Technologies Ltd.
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
P.O. Box 2151
Amherst, Massachusetts 01004-2151

Re: K200582
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: May 6, 2020
Received: May 6, 2020

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,

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)*
K200582

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

Heyer Regulatory Solutions LLC
P.O. Box 2151
Amherst, MA 01004-2151
Contact: Sheila Hemeon-Heyer
Sheila@heyer-regulatory.com

B. Manufacturer/ 510(k) Applicant:

Bend It Technologies, Ltd
25 Basel Street
Petach Tikva 4951038, Israel
Contact: Simona Beilin-Nissan
Title: VP Clinical and Regulatory Affairs
Tel #: +972 3 6747377
Email: simonabn@benditttech.com

C. Date Prepared: June 17, 2020

D. Device Name and Classification Information:

Trade Name:	Bendit2.7™ Steerable Microcatheter
Common/Usual Name:	Diagnostic Intravascular Catheter
Regulation:	21 CFR 870.1200
Product Code:	KRA
Review Panel:	Cardiovascular
Class:	II

E. Predicate Device: Bendit2.7™ Steerable Microcatheter, K190126

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 distal 80 cm of 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 previously cleared Bendit2.7™ devices. The similarities and differences between the proposed and predicate devices are discussed following the table.

	Predicate Device Bendit2.7™ cleared under K190126	**Proposed Device Modified Bendit2.7™**	**Comparison**
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 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.	Same
Catheter type	Steerable microcatheter	Steerable microcatheter	Same
Microcatheter Components	Catheter shaft, steerable deflecting tip, steering handle	Catheter shaft, steerable deflecting tip, steering handle	Same
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	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	Same

	Predicate Device Bendit2.7™ cleared under K190126	Proposed Device Modified Bendit2.7™	Comparison
	laser-cut patterns that provide tip flexibility. Material injection via syringe connection to luer at proximal end of catheter.	laser-cut patterns that provide tip flexibility. Material injection via syringe connection to luer at proximal end of catheter.	
Catheter OD	2.7 Fr	2.7 Fr	Same
Catheter ID	0.021"	0.021”	Same
Catheter shaft length	130 cm	130 cm	Same
Hydrophilic coating on shaft	Yes, 130 cm	Yes, 80 cm	Change
PTFE coating on inner tube	No	Yes	Change
Inner connection tube	Yes	No	Change
Compatible guidewire	≤ 0.018"	≤ 0.018”	Same
# Lumens	Single	Single	Same
Fill volume	0.45 mL	0.45 mL	Same
Max injection pressure	1000 psi	1000 psi	Same
Deflecting tip	Yes	Yes	Same
Max tip deflection angle	180° from neutral position in one direction	180° from neutral position in one direction	Same
Max tip rotation	100° in both directions (clockwise and counter clockwise)	100° in both directions (clockwise and counter clockwise)	Same
Radiopaque	Yes, radiopaque (70% tungsten) tip	Yes, radiopaque (80% tungsten) tip	Change
Steering mechanism	Slider used to deflect tip Knob used to rotate tip	Slider used to deflect tip Knob used to rotate tip	Same
Steering lock mechanism	Yes	Yes	Same
Max microsphere size	700 µm	700 µm	Same
Max coil size	0.018" (0.46 mm)	0.018" (0.46 mm)	Same

	Predicate Device Bendit2.7™ cleared under K190126	Proposed Device Modified Bendit2.7™	Comparison
Biocompatibility	Complies with all required testing per FDA guidance for application of ISO 10993-1	Complies with all required testing per FDA guidance for application of ISO 10993-1	Same
Use restriction	Single-use, disposable	Single-use, disposable	Same
Sterilization	Ethylene oxide, SAL 10^{-6}	Ethylene oxide, SAL 10^{-6}	Same

I. Discussion of Differences

Four design changes have been made to the Bendit2.7™ Steerable Microcatheter. The changes are to improve ease of use and do not change the device indications for use, introduce any new functionality, change or introduce any new risks, or change the fundamental scientific technology of the device.

1. The length of hydrophilic coating on the catheter shaft is reduced to cover the distal 80 cm instead of the entire 130 cm length. This change is to facilitate user handling of the catheter shaft portion that does not enter the body.
2. The amount of Tungsten in the catheter tip is increased from 70% to 80% to improve tip visibility on imaging.
3. A PTFE coating is added to the outer surface of the inner tube to decrease friction within the catheter during bending.
4. The inner connection tube was removed as it was determined not to be necessary for sufficient bond strength at the luer / inner tube connection.

J. Testing to Support Substantial Equivalence

The following tests were conducted to verify the design changes resulting in the modified device:

1. Visual inspections and dimensional verifications
2. Tensile bond strength at the tip and luer connections
3. Torsional bond strength
4. Kink resistance
5. Power Injection (for Flowrate and Device Pressure)
6. Coating integrity
7. Corrosion
8. Pushability, Retraction, and Torqueability
9. Simulated use validation testing, including trackability
10. Chemical characterization according to ISO 10993-17-2020 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances and a toxicological risk assessment

All test results met the pre-defined test acceptance criteria.

No animal or clinical tests were required to validate the changes to the Bendit2.7™ Steerable Microcatheter.

K. Conclusion

The information and testing presented in this 510(k) demonstrate that the modified Bendit2.7™ Steerable Microcatheter is substantially equivalent to the original Bendit2.7 Steerable Microcatheter previously cleared under K190126.