May 3, 2018

Cook Incorporated
Mr. Daniel Corbin
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K172980
Trade/Device Name: Micropuncture Pedal Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 4, 2018
Received: April 5, 2018

Dear Mr. Corbin:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172980

Device Name
Micropuncture® Pedal Access Set

Indications for Use *(Describe)*
Indications for Use for the Micropuncture® Pedal Access Set:

This device is intended to introduce up to an 0.038" wire guide into the peripheral vasculature. It is also used to introduce diagnostic and/or interventional devices able to pass through the ID of the introducer.

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

Micropuncture® Pedal Access Set
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
Address:	750 Daniels Way
	Bloomington, IN 47404
Contact:	Daniel J. Corbin
Email:	RegSubmissions@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 104018
Contact Fax Number:	812-332-0281

Date Prepared:	03 May 2018

Device Information

Trade Name:	Micropuncture® Pedal Access Set
Common Name:	Introducer, Catheter
Classification Name:	Catheter Introducer
	DYB (21 CFR §870.1340)

Predicate Device

The predicate device of the Micropuncture® Pedal Access Set is the Micropuncture® Introducer Set, cleared under K133114.

Reference Device

The Performer® Introducer, cleared under K171999, is a reference device for the subject device, the Micropuncture® Pedal Access Set.

Comparison to Predicate

It has been demonstrated that the Micropuncture® Pedal Access Set and the predicate device are substantially equivalent in terms of intended use, duration of use, principles of operation, fundamental technological characteristics, and insertion method. The design, dimensions, indications for use, duration of use, and materials of the subject device are similar to the attributes of the predicate device. The predicate coaxial introducer/dilator pair are available in 4.0 or 5.0 French diameters and 10 centimeter length; the subject coaxial introducer/dilator pair is available in 4.0 or 5.0 French diameters and 7 centimeter length. The wire guide component in the predicate device is available in length of 40 centimeters and subject set is available as 40 centimeters in length. The predicate wire guide is manufactured from nitinol and palladium; the wire guide in the subject device set is made from nitinol and platinum. The needle components are identical in both the predicate and subject devices. The subject device comes with a Check-Flo® Hemostasis Valve, as where the predicate device does not contain a hemostasis valve. The differences between the subject device and the predicate device, including components, device dimensions, materials, and indications for use, do not raise new questions of safety and effectiveness as demonstrated by performance testing.

Device Description

The device is utilized to gain access to the peripheral vasculature using the Seldinger technique. These introducer sets are comprised of either 4.0 French or 5.0 French outer introducer and 3.0 French inner dilator coaxial pair, a 21 gauge percutaneous entry needle, an 0.018 inch mandril wire guide with a distal coil tip, and a Check-Flo® Hemostasis Valve. These sets are supplied sterile and are intended for one-time use.

Intended Use

This device is intended to introduce up to an 0.038” wire guide into the peripheral vasculature. It is also used to introduce diagnostic and/or interventional devices able to pass through the ID of the introducer.

Clinical Literature

The following articles provide evidence for the use of the subject device, the Micropuncture® Pedal Access Set, for its indications for use:

Walker CM, Mustapha J, Zeller T, et al. Tibiopedal Access for Crossing of Infrainguinal Artery Occlusions: A Prospective Multicenter Observational Study. *Journal of Endovascular Therapy*. 2016; 23(6): 839-846.

Goltz JP, Planert M, Horn M, et al. Retrograde Transpedal Access for Revascularization of Below-the-Knee Arteries in Patients with Critical Limb Ischemia after an Unsuccessful Antegrade Transfemoral Approach. *Fortschr Röntgenstr* 2016; 188: 940–948.

El-Sayed H, Bennett M, Loh T, Davies M. Retrograde Pedal Access and Endovascular Revascularization: A Safe and Effective Technique for High-Risk Patients with Complex Tibial Vessel Disease. *Annals of Vascular Surgery*. 2016; February; 31: 91-98.

These articles describe successful use of the subject device for pedal access in a total of 220 patients, and support the use of the subject device for its indications for use.

Test Data

The Micropuncture® Pedal Access Set, subject of this submission, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time) demonstrated that the device is biocompatible. In conformance with the applicable sections of ANSI AAMI ISO 10993-1:2009(R)2013, the predetermined acceptance criteria were met.

- Tensile Testing of the Hub to Shaft Bond – Testing verified that the hub of the outer introducer and inner dilator would not loosen or separate from the shaft when tested in accordance with BS EN ISO 11070:2014. The predetermined acceptance criteria were met.

- Tensile Testing of the Connection Bonds of the Check-Flo® Valve – Testing verified that under proper clinical use of the hemostasis valve, the connection bonds are expected to withstand peak load values. The predetermined acceptance criterion was met.

- Liquid Leakage Testing – Testing in accordance with BS EN ISO 11070:2014 – Sections 7.3 and 7.4 verified that under proper clinical use of the hemostasis valve, there shall be no liquid leakage. The predetermined acceptance criterion was met.

- Dimensional Verification Testing – Testing verified that the components of the Micropuncture® Pedal Access Set would meet the specified dimensional requirements. The predetermined acceptance criteria were met.

- Wire Guide Fracture Test – Testing in accordance with BS EN ISO 11070:2014 – Section 8.4 and Annex H verified that the wire guide would show no signs of fracture when subjected to the resistance to fracture testing. The predetermined acceptance criterion was met.

- Wire Guide Tensile Test – Testing in accordance with BS EN ISO 11070:2014 – Section 8.6 and Annex H verified that the distal tip of the wire guide would not separate under clinically relevant conditions. The predetermined acceptance criterion was met.

- Radiopacity Testing – Testing verified that the wire guide would be detectable under fluoroscopy. The predetermined acceptance criterion was met.

- Resistance to Damage by Flex Testing – Testing in accordance with BS EN ISO 11070:2014 – Section 8.5 and Annex G verified that the wire guide would not show any damage or defects when subjected to repeated flexing. The predetermined acceptance criterion was met.

In conclusion, the results of these tests support a determination of substantial equivalence.