December 20, 2017

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

Re: K171275
Trade/Device Name: Micropuncture Introducer Set, Micropuncture Introducer Set with Push-Plus Design, Micropuncture Introducer Set with Silhouette Transitionless Design, Micropuncture Introducer Set with Silhouette Transitionless Design and Push-Plus Design
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 20, 2017
Received: November 21, 2017

Dear Daniel 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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)*

K171275

Device Name

Micropuncture Introducer Set, Micropuncture Introducer Set with Push-Plus Design, Micropuncture Introducer Set with Silhouette Transitionless Design, Micropuncture Introducer Set with Transitionless Design and Push-Plus Design

Indications for Use *(Describe)*

Indications for Use for the Micropuncture® Introducer Set:

The Micropuncture® Introducer Set is intended for the placement of wire guides up to 0.038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

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 – K171275

Submitted By:

Daniel J. Corbin
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x104018
Fax: (812) 332-0281
Date Prepared: April 28, 2017

Device:

Trade Name:
Micropuncture® Introducer Set
Micropuncture® Introducer Set with Push-Plus™ Design
Micropuncture® Introducer Set with Silhouette® Transitionless Design
Micropuncture® Introducer Set with Silhouette® Transitionless Design and Push-Plus™ Design

Common Name: Introducer Catheter
Classification Name: Catheter, Introducer
DYB (21 CFR §870.1340)

Indications for Use:

The Micropuncture® Introducer Set is intended for the placement of wire guides up to 0.038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, the Micropuncture® Introducer Set cleared under 510(k) number K133114. Reference devices include the VSI Micro-Introducer Set (K101604), the VSI InnerChange Micro-Introducer Catheter (K062627), the VSI Guidewire (K112631), and Cook Inc. Flexor Tuohy-Borst Side-Arm Introducer, Ansel Modification (K142829).

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Comparison to Predicate Device:

The Micropuncture® Introducer Set is substantially equivalent to the predicate devices, the Micropuncture® Introducer Set (K133114), in that these devices have the same intended use, identical method of sterilization, method of operation, and similar fundamental technological characteristics. The predicate, K133114, is available in 4 or 5 French, 10 centimeter in length coaxial introducer/dilator pair, 40 centimeter in length 0.018 inch mandrel wire guide, and 21 gage, 7 centimeter in length entry access needle. The range of available lengths of the introducer/dilator, wire guide, and needle will increase with this submission to include a range of 4.5 to 60 centimeter introducer/dilator pair, 30 to 130 centimeter wire guide, and 2.5 to 15 centimeter needle; however, the outer diameters of each component will remain the same as the predicate, K133114. Additional materials of constructions, additional devices dimensions, and additional variations of set components have been included in this submission in order to expand the product line. This submission will also add sideports to the 4 and 5 French introducers, as well as a Y-Connector Hemostasis Valve to a limited number of sets. The substantial equivalence of the modified device to the predicate device is supported by biocompatibility and benchtop performance testing.

Device Description:

The Micropuncture® Introducer Set is intended for the placement of wire guides up to 0.038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired. The device is utilized to gain access to the 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 gage percutaneous entry needle, and a 0.018 inch mandrel wire guide with a distal coil tip. The dilator of these sets can come with a stainless steel stiffening cannula embedded in the shaft. These sets are supplied sterile and are intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the Micropuncture® Introducer Set met applicable design and performance requirements and support a determination of substantial equivalence.

- Biocompatibility – Testing, in conformance with ANSI AAMI ISO 10993-1:2009(R)2013, shows the device is biocompatible. Cytotoxicity, Pyrogen, Sensitization,

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Intracutaneous Reactivity, Acute Systemic Toxicity, Complement Activation, and Hemocompatibility testing were all performed, completed, and passed. The predetermined acceptance criteria were met.

- Liquid Leakage Testing: Testing verified that under proper clinical use of the outer introducer sheath and Y-Connector, each test article shall not leak when tested in accordance with BS EN ISO 11070:2014, Annex D and E. The predetermined acceptance criteria were met.
- Tensile Test of the Hub to Shaft Bond – Testing verified that the hub of the outer introducer, inner dilator, and needle 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 Test of the Sideported Section – Testing verified that the sideported section of the outer introducer shaft would not separate under clinically relevant conditions. The predetermined acceptance criterion was met.
- Dimensional Verification Testing – Testing verified that the components of the Micropuncture Introducer Sets met the dimensional requirements in terms of overall length, inner diameter, outer diameter, and component compatibility. The predetermined acceptance criteria were met.
- Evaluation of Corrosion Resistance – Testing verified that the metallic components of the set would resist corrosion. The predetermined acceptance criteria were met.
- Insertion Force Test – Testing simulated percutaneous insertion force through a simulated skin membrane. The predetermined acceptance criteria were met.
- Wire Fracture Test – Testing verified that the wire guide would show no signs of fracture when subjected to the resistance to fracture testing. The predetermined acceptance criteria were met.
- Wire Tensile Test – Testing verified that the distal tip of the wire guide would not separate under clinically relevant conditions. The predetermined acceptance criteria were met.
- Radiopacity Testing – Testing verified that the wire guide would be detectable under fluoroscopy. The predetermined acceptance criteria were met.
- Resistance to Damage by Flex Testing – Testing verified that the wire guide would not show any damage or defects when subjected to repeated flexing. The predetermined acceptance criteria were met.

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