March 25, 2024

Cook Medical
David Lehr
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, Indiana 47404

Re: K240589
Trade/Device Name: Micropuncture Introducer Sets
Micropuncture Pedal Access Sets
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 1, 2024
Received: March 1, 2024

Dear David Lehr:

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 device 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.

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2024.03.25 15:51:13 -04'00'

For
Misti Malone
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240589

Device Name
Micropuncture® Introducer Sets
Micropuncture® Pedal Access Sets

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

As required by 21 CFR §807.92
Date Prepared: March 1, 2024

Submitted By:

Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 325-4172
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Micropuncture Introducer Sets Micropuncture Pedal Access Sets
Common Name:	Introducer, catheter
Classification Name:	Catheter introducer
Classification Panel:	Cardiovascular
Regulation/Product Code:	21 CFR §870.1340/DQY
Class/Panel:	Class II/Cardiovascular

Predicate Device:

Micropuncture® Access Sets (K171275), manufactured by Cook Incorporated.

Reference Device:

Micropuncture® Pedal Access Sets (K172980), manufactured by Cook Incorporated.

Device Description:

The Micropuncture® Introducer Sets and Micropuncture® Pedal Access Sets are utilized to gain access to the vasculature using the Seldinger technique. These introducer sets are composed of either a 4.0 French or a 5.0 French outer sheath and a 3.0 French inner dilator coaxial pair, a 21 gage percutaneous entry needle, a 0.018 inch mandrel wire guide with a distal coil tip, and (optionally) a Check-Flo® Hemostasis valve, a Tuohy-Borst Sidearm Adapter, and a wire guide inserter. 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.

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.

The Micropuncture® Pedal Access Set 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.

Comparison of Technological Characteristics to Predicate:

It has been demonstrated that the Micropuncture® Introducer Sets and Micropuncture® Pedal Access Sets are substantially equivalent to the predicate device, the Micropuncture® Introducer Sets (K171275) and the reference device, the Micropuncture® Pedal Access Sets (K172980), respectively, in terms of materials and methods of construction, principles of operation, and basic technological characteristics. The indications for use of the subject devices are identical to those of the predicate and reference devices. Modifications include an update to the hub design on the outer sheaths and inner dilators of most introducers.

Technological Characteristics:

The subject devices, the Micropuncture® Introducer Sets and Micropuncture® Pedal Access Sets, were subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below.

<u>Introducer Performance Testing</u>

- Tensile – The hub-to-shaft bonds of the 4 Fr and 5 Fr outer sheaths were tested for tensile strength in accordance with ISO 11070 at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Tensile – The hub-to-shaft bonds of the inner dilators (with both stiffened cannula and non-stiffened cannula) were tested for tensile strength in accordance with ISO 11070 at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Liquid Leakage – Both the 4 Fr and 5 Fr outer sheaths were tested for liquid leakage in accordance with Annex D of ISO 11070 at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.

Luer Performance Testing in accordance with ISO 80369-7

- Falling Drop Positive Pressure Liquid Leakage – The redesigned introducer hubs were tested for liquid leakage in accordance with ISO 80369-7, Section 6.1.3, and ISO 80369-20, Annex C, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Sub-Atmospheric Pressure Air Leakage – The redesigned introducer hubs were tested for air leakage in accordance with ISO 80369-7, Section 6.2, and ISO 80369-20, Annex D, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Stress Cracking – The redesigned introducer hubs were tested for stress cracking in accordance with ISO 80369-7, Section 6.3 and ISO 80369-20, Annex E, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Resistance to Separation from Axial Load – The redesigned introducer hubs were tested for separation from axial load in accordance with ISO 80369-7, Section 6.4, and ISO 80369-20, Annex F, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Resistance to Separation from Unscrewing – The redesigned introducer hubs were tested for resistance to separation from unscrewing in accordance with ISO 80369-7, Section 6.5, and ISO 80369-20, Annex G, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.
- Resistance to Overriding – The redesigned introducer hubs were tested for resistance to overriding in accordance with ISO 80369-7, Section 6.6, and ISO 80369-20, Annex H, at both time 0 and 3-year accelerated aging. The predetermined acceptance criteria for all studies were met.

Validation

- Non-Rotating Hub Cap Summative Evaluation – This analysis was conducted via an Expert Review of the proposed hub design update in comparison to the current hub design in accordance with Annex K of AAMI/IEC TIR62366-2:2016 and Table A.2 of ANSI/AAMI HE75:2009/(R)2018. The acceptance criteria for this evaluation were met.

Conclusion:

The results of these tests support a conclusion that the Micropuncture® Introducer Sets and the Micropuncture® Pedal Access Sets, subject of this submission, met the design input requirements based on the devices' intended uses and that they are substantially equivalent to the predicate

and reference devices, the Micropuncture® Introducer Sets (Cook Incorporated, K171275) and the Micropuncture® Pedal Access Sets (Cook Incorporated, K172980).