January 10, 2019

Cook Incorporated
David Lehr
Regulatory Affairs Manager
750 Daniels Way
Bloomington, Indiana 47404

Re: K183036
Trade/Device Name: Dilator Sets
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE, FGE
Dated: December 21, 2018
Received: December 26, 2018

Dear Mr. Lehr:

This letter corrects our substantially equivalent letter of December 20, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Misti L. Malone -S

For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183036

Device Name
Dilator Sets

Indications for Use *(Describe)*
Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.

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: December 21, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102309
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Dilator Sets
Common Name:	Dilator, vessel, for percutaneous catheterization/ Stents, drains and dilators for the biliary ducts
Classification Panel:	Cardiovascular/Gastroenterology/Urology
Regulation:	21 CFR §870.1310, 21 CFR §876.5010
Product Code:	DRE, FGE

Predicate Devices:

- Medcomp® Vessel Dilator (Medcomp®, K162389)
- PBN Dilators (Medical Device Technologies, Inc., K990808)

Reference Devices:

- Peel-Away Introducer Set (Cook Inc., K170020)
- Royal Flush Catheter (Cook Inc., K171264)
- CrossCath Support Catheter (Cook Inc., K161801)

Device Description:

Cook Dilator Sets may consist of either a single dilator or a group of components that are used percutaneously to dilate puncture sites or catheter tracts, thereby facilitating the placement of other therapeutic or diagnostic devices into a natural body space (e.g., the peritoneal cavity, an artery or vein) for various vascular or non-vascular clinical applications. Some Dilator Set configurations may also include an entry needle and wire guide. The dilator component of the Dilator Sets is available in diameters ranging from 3.0 to 26.0 French and in lengths ranging from 6 to 65 cm. The broad range of dilator sizes accommodates the variation in the size of the

devices that could be inserted through the initial access site. All configurations of the Dilator Sets are supplied as packaged, sterile devices, intended for single-patient use.

Intended Use:
Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.

Comparison of Technological Characteristics to Predicate:
The Dilator Sets and the predicate devices have the same basic intended use. The subject device is similar in technological characteristics (i.e., design and materials) to those of the predicate devices, with the addition of a smaller dilator diameter of 3.0 Fr and a broader scope of lengths (6 to 65 cm) as compared to the predicate devices, which have a combined scope of lengths ranging from 15 to 35 cm. Some configurations of the subject device are also supplied with additional kit components (i.e., entry needle and wire guide) as compared to the predicate devices.

Technological Characteristics:
The subject device, Dilator Sets, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests performed are listed below:

- Biocompatibility – Tested in accordance with ISO 10993-1:2009. The pre-determined acceptance criteria were met.
- Dilator Hub to Shaft Tensile – Tested in accordance with ISO 11070:2014. The pre-determined acceptance criteria were met.
- Compatibility Testing – Tested in accordance with an approved study protocol. The pre-determined acceptance criterial were met.
- Dimensional Verification Testing – Tested in accordance with an approved study protocol. The pre-determined acceptance criteria were met.
- Radiopacity Evaluation – Tested in accordance with ASTM F640-12. The pre-determined acceptance criteria were met.
- Dilator Tip Rollback Testing – Tested in accordance with ISO 11070:2014, Annex A.3. The pre-determined acceptance criteria were met.
- Kink Radius Testing – Tested in accordance with ISO 11070:2014, Annex A. The pre-determined acceptance criteria were met.

- Lubricity Testing – Tested in accordance with an approved study protocol. The pre-determined acceptance criterial were met.

Conclusion:

The results of these tests support a conclusion that the Dilator Sets, subject of this submission, met the design input requirements based on the devices' intended use and support the conclusion these devices do not raise new questions of safety and/or effectiveness. The results of these tests support a determination of substantial equivalence to the predicate devices, the Medcomp® Vessel Dilator (Medcomp®, K162389) and the PBN Dilators (Medical Device Technologies, Inc., K990808).