April 6, 2021

Cook Incorporated
Michael Venezia
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K210734
Trade/Device Name: Endovascular Dilator and Sets
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: March 10, 2021
Received: March 11, 2021

Dear Michael Venezia:

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2021.04.06 08:43:00 -04'00'

Finn Donaldson
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)*

K210734

Device Name
Endovascular Dilator and Sets

Indications for Use *(Describe)*
Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular applications in the arterial system.

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
Endovascular Dilator and Endovascular Dilator Sets
As required by 21 CFR §807.92
Date Prepared: March 9, 2021

Submitted By:

Applicant:	Cook Incorporated
Contact:	Michael Venezia
Applicant Address:	750 Daniels Way Bloomington, IN 47404 Phone: (812) 325-4172 Fax: (812) 332-0281

Device:

Submission:	Special 510(k) Premarket Notification
Trade Name:	Endovascular Dilator and Sets
Common Name:	Vessel dilator for percutaneous catheterization
Classification Name:	Dilator, Vessel, For Percutaneous Catheterization
Regulation/Product Code:	21 CFR §870.1310/DRE
Class/Panel:	Class II/Cardiovascular

Indications for Use:

Intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular applications in the arterial system.

Predicate Device:

The device subject of this submission is substantially equivalent to the predicate device, the Dilator Sets, cleared under 510(k) number K183036.

Comparison to Predicate Device:

It has been demonstrated that the Endovascular Dilator and Sets are comparable to the predicate device. The subject devices are similar to the predicate device in terms of intended use and identical in terms of principles of operation, materials of construction, and basic technological characteristics. The intended use has been updated to remove venous and non-vascular applications from the Instructions for Use and the intended use statement.

Device Description:

Endovascular Dilator and Sets are manufactured from vinyl radiopaque dilator tubing and consist of either one or two dilators that are used percutaneously to dilate puncture sites or catheter tracts, thereby facilitating the placement of other therapeutic or diagnostic devices into an artery for vascular clinical applications that require percutaneous access. The serial dilator components are designed with long, gradual tapers and include hydrophilic coating, and are available in various inner and outer diameter and length combinations.

Test Data:

There are no device, material, or design changes to any of the devices included in the Endovascular Dilator and Sets. Since there is no design change to the device subject of this submission, the testing that was provided for the predicate device in submission K183036 remains to support this submission. No additional testing or design control activities or risk assessment are required to support substantial equivalence.

Conclusion:

Because no changes are being made to the Endovascular Dilator and Sets, the information provided in this submission supports a determination of substantially equivalence to the predicate device, the Dilator Sets (K183036).