December 20, 2017

Cook Incorporated
Colin Jacob
Regulatory Affairs Specialist
750 Daniels Way P.O. Box 489
Bloomington, Indiana 47402

Re: K173685
Trade/Device Name: Peel-Away Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, KNT
Dated: November 30, 2017
Received: December 1, 2017

Dear Colin Jacob:

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)*

K173685

Device Name
Peel-Away Introducer Set

Indications for Use *(Describe)*

The Peel-Away Introducer Set is intended for the percutaneous introduction of balloon, electrode and closed or non-tapered end catheters into central and peripheral vasculature, and for nonvascular use.

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 **K173685**

Submitted By:

Applicant: Cook Incorporated
Contact: Colin Jacob
Applicant Address: Cook Incorporated
P.O. Box 489
750 Daniels Way
Bloomington, IN 47402
Contact Phone Number: (812) 335-3575 x 104965
Contact Fax Number: (812) 332-0281

Device Information:

Trade Name: Peel-Away Introducer Set
Classification Name: Introducer, Catheter
Panel: Cardiovascular
Regulation: 21 CFR § 870.1340
Regulation name: Catheter introducer
Product Code: DYB; KNT

Predicate Device:

- Peel-Away Introducer Set (K170020)

Device Description:

The Peel-Away Introducer Set is a single-use, sterile, disposable product that is used to provide initial percutaneous access. It is comprised of a co-axial introducer assembly (peel-away sheath and dilator). Set may contain a wire guide in a size fitted to the endhole of the dilator and may contain an access needle in a gage that allows the included wire guide to pass through its lumen. Additional set components (e.g., luer-slip syringe) are available.

Indications for Use:

The Peel-Away Introducer Set is intended for the percutaneous introduction of balloon, electrode and closed or nontapered end catheters into central and peripheral vasculature, and for non-vascular use.

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Comparison to Predicates:

The Peel-Away Introducer Set and the predicate device, Peel-Away Introducer Set (K170020), are substantially equivalent in that these devices have the same intended use and principle of operation, basic design, and functional characteristics. The only differences between the subject and predicate device are the materials and additional lengths as stated in the comparison table below.

		Predicate Device	Subject Device
		Peel-Away Introducer Set (K170020)	**Peel-Away Introducer Set**
Manufacturer		Cook Incorporated	IDENTICAL TO PREDICATE
Regulation		21 CFR § 870.1340, 21 CFR § 876.5980	IDENTICAL TO PREDICATE
Product Code		DYB, KNT	IDENTICAL TO PREDICATE
Classification		II	IDENTICAL TO PREDICATE
Indications for Use		The Peel-Away Introducer Set is intended for the percutaneous introduction of balloon, electrode and closed or nontapered end catheters into central and peripheral vasculature, and for non-vascular use.	IDENTICAL TO PREDICATE
Fundamental Scientific Technology		Initial percutaneous access for temporary working channel	IDENTICAL TO PREDICATE
Duration of use		Limited (≤ 24 hours)	IDENTICAL TO PREDICATE
Design		Introducer assembly includes an outer peelable sheath and an inner dilator. Peelable sheath has a winged hub to facilitate a tear in the sheath.	IDENTICAL TO PREDICATE
Shape		Outer sheath: winged hub, cylindrical cannula	IDENTICAL TO PREDICATE
		Inner Dilator: Round hub, cylindrical cannula	IDENTICAL TO PREDICATE
Dimensions	**Introducer Assembly Diameter**	3.5-26 Fr	3.5-18 Fr
	Sheath Length	7, 9, 13, 15.5 cm	8, 9, 10, 24, 30, 47 cm
	Dilator Length	11, 13, 20 cm	13.5, 16, 16.5, 20, 35, 37, 51.5
	Wire Guide Diameter	0.018, 0.021, 0.025, 0.035, 0.038 in	0.018 and 0.038 in
	Wire Guide Length	30, 50, 70, 100 cm	50, 65, 85 cm
Materials	**Sheath**	Thick Wall Sheathing Radiopaque TFE (VRTS)	6.0 to 18 Fr –VAD[-CVI] modification: Thick Wall Sheathing Radiopaque TFE (VRTS) 3.5 to 7.5 Fr -DENNY modification: TFE
	Dilator	3.5 to 12 Fr: Radiopaque Polyethylene 13 to 26 Fr: Vinyl	3.5 to 7.5 Fr -DENNY modification: Radiopaque Polyethylene 6.0 to 18 Fr –VAD[-CVI] modification: TFE Radiopaque Tubing

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	Predicate Device	Subject Device
	Peel-Away Introducer Set (K170020)	**Peel-Away Introducer Set**
Wire Guide	Stainless Steel Solder	Stainless Steel / Solder Nitinol / Platinum / Solder
Additional Set Components	Entry access needle, needle holder cup, luer-slip syringe, serial dilators, thumb scalpel	Entry access needle and luer-slip syringe
Shelf Life	Three years	IDENTICAL TO PREDICATE
Sterilization Process	Ethylene Oxide	IDENTICAL TO PREDICATE
Sterility Assurance Level	10^{-6}	IDENTICAL TO PREDICATE

Technological Characteristics:

The subject device, Peel-Away Introducer Set, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests have been conducted to ensure reliable design and performance under the specified testing parameters.

- Biocompatibility Testing – Testing was performed in accordance with BS EN ISO 10993-1:2003, the material and methods used to manufacture the subject device are non-toxic and met the acceptance criteria for their intended use.
- Introducer Assembly (Radiopacity – Accelerated) - Test articles must demonstrate that the shaft gradient shall fall along the gradient of an aluminum X-ray step wedge gauge, following the method described in ASTM F6540-12, “Standard Test Methods For Determining Radiopacity for Medical Use.” Test results met predetermined criteria.
- Introducer Dilator (Tensile Testing – Accelerated) – Test article must demonstrate that 90% of test articles at the 95% confidence can be expected to meet or exceed therequirements of BS EN ISO 11070: 2014. Test results met predetermined criteria.
- Introducer Sheath (Peel Force Testing– Accelerated) - Characterization of peel force for various Peel-Away Introducer sheath sizes was successfully performed.
- Wire Guide (Corrosion, Flex, Fracture and Tensile Testing – Accelerated)- Test article must shall not show signs of corrosion, defect, damage, fracture that could affect their functional performance. Test articles must also demonstrate per the standard, minimal tensile strength for wire guides with having a certain diameter size. Test results met predetermined criteria.

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