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

Re: K170020  
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: August 28, 2017  
Received: August 29, 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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 non-vascular use.
510(k) Summary

Cook Incorporated – Traditional 510(k) K170020

Peel-Away® Introducer Sets
August 28, 2017

510(k) Summary

Peel-Away® Introducer Sets (21 CFR §870.1340, 21 CFR §876.5980)
Date Prepared: August 28, 2017

Submitted By:
Applicant: Cook Incorporated
Contact: Colin Jacob
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN  47404
Contact Phone Number: (812) 335-3575 x 104965
Contact Fax Number: (812) 332-0281

Device Information:
Trade Name: Peel-Away® Introducer Set
Common Name: Introducer, Catheter; Tube, Gastro-Enterostomy
Classification Name/Panel: Catheter Introducer, Gastrointestinal tube and accessories – Gastroenterology/Urology, Cardiovascular
Regulation: 21 CFR §876.5980, 21 CFR §870.1340
Product Code: DYB, KGC

Predicate Devices:
- Primary: Galt Medical Tearaway Introducer Sheath (K153533)
- Secondary: Kimberly-Clark Enteral Access Dilation System (K093312)

Device Description:
Cook’s Peel-Away® Introducer Sets are single-use, sterile, disposable products that are used to provide initial percutaneous access. They are comprised of a co-axial introducer assembly (peel-away sheath and dilator). Sets 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, thumb scalpel) are available.

Indications for Use:
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 non-vascular use.
## Comparison to Predicates:

<table>
<thead>
<tr>
<th>SUBJECT DEVICE</th>
<th>PRIMARY PREDICATE</th>
<th>SECONDARY PREDICATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peel-Away® Introducer Sets</td>
<td>Tearaway Introducer Sheath</td>
<td>Kimberly-Clark Enteral Access Dilation System</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Cook Incorporated</th>
<th>Galt Medical Corp.</th>
<th>Kimberly-Clark Corporation Halyard</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k)</td>
<td>K170020</td>
<td>K153533</td>
<td>K093312</td>
</tr>
<tr>
<td>Product Code</td>
<td>DYB, KGC</td>
<td>DYB</td>
<td>KGC</td>
</tr>
<tr>
<td>Classification</td>
<td>IDENTICAL TO PREDICATES</td>
<td>II</td>
<td>II</td>
</tr>
</tbody>
</table>

**Indications for Use**

- **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 non-vascular use.
- **Adult Only – Tearaway Introducer Sheath**: The introducer is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.*

**Patient Population**

- Adults
- Adults
- Adults

**Placement**

- IDENTICAL TO PREDICATES
- Percutaneous
- Percutaneous

**Clinical Application**

- General (i.e., for vascular and non-vascular use)
- Vascular use
- Non-vascular use (specifically for placement of feeding tubes)

**Design**

- IDENTICAL TO PREDICATES

- **Galt Tearaway Introducers assembly includes outer peelable sheath and a dilator. Peelable sheath has a winged hub to facilitate the tear in the sheath.**
- **Kimberly Clark Peel-Away Introducers assembly includes outer peelable sheath and a dilator. Peelable sheath has a winged hub to facilitate the tear in the sheath.**

**Shape**

- IDENTICAL TO PREDICATES

- **Introducer Sheath: winged hub, cylindrical cannula**
  - Dilator: Round hub, cylindrical cannula
- **Introducer Sheath: winged hub, cylindrical cannula**
  - Dilator: Round hub, cylindrical cannula

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* K153533 was a bundled submission that included 2 to 3 Fr sizes for adult and pediatric use.
## Comparison to Predicates (continued):

<table>
<thead>
<tr>
<th>SUBJECT DEVICE</th>
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<tr>
<td><strong>Peel-Away® Introducer Sets</strong></td>
<td>Tearaway Introducer Sheath</td>
<td>Kimberley-Clark Enteral Access Dilation System</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introducer (Dilator + Sheath) Diameter</td>
<td>3.5-26 Fr</td>
<td>3-16 Fr</td>
</tr>
<tr>
<td>Dilator Length</td>
<td>11, 13, 20 cm</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sheath Length</td>
<td>7, 9, 13, 15.5 cm</td>
<td>Unknown</td>
</tr>
<tr>
<td>Wire Guide Diameter</td>
<td>0.018, 0.021, 0.025, 0.035, 0.038 in</td>
<td>0.008, 0.010, 0.014, 0.018, 0.035, 0.038 in</td>
</tr>
<tr>
<td>Wire Guide Length</td>
<td>30, 50, 70, 100 cm</td>
<td>20, 40, 60 cm</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dilator</td>
<td>3.5 to 12 Fr: Radiopaque Polyethylene 13 to 26 Fr: Vinyl</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sheath</td>
<td>Thick Wall Sheathing Radiopaque TFE (VRTS)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Wire Guide</td>
<td>Stainless Steel Solder</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Additional Set Components</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry access needle, needle holder cup, luer-slip syringe, serial dilators, thumb scalpel</td>
<td>Entry access needles, additional serial dilators</td>
<td>Entry access needle, syringe, #11 safety scalpel, gauze pads, catheter tip syringe, introducer cannula</td>
</tr>
<tr>
<td><strong>Duration of Use</strong></td>
<td>IDENTICAL TO PREDICATES</td>
<td>Single Use Limited Duration (≤ 24 hours)</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>3 years</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Sterilization Process</strong></td>
<td>IDENTICAL TO PREDICATES</td>
<td>Ethylene oxide</td>
</tr>
</tbody>
</table>
Technological Characteristics:

The proposed device, Peel-Away® Introducer Sets, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

- Introducer knob to Shaft Tensile - Test articles must meet the force break requirements. Test results met predetermined criteria.
- Peel Force – Characterization of peel force for various Peel-Away Introducer sheath sizes was successfully performed.
- Dilator Hub to Shaft Tensile - Test articles must statistically demonstrate that 90% of test articles at the 95% confidence can be expected to meet or exceed the requirements of BS EN ISO 11070: 2014. Test results met predetermined criteria.
- Radiopacity Evaluation - 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.
- Wire guide Corrosion evaluation - Wire guides should not have any visual evidence of corrosion that could affect their functional performance. Test results met predetermined criteria.
- Wire Guide Fracture evaluation - The wire shall not fracture when wound around an appropriate former for at least three complete turns. Test results met predetermined criteria.
- Wire Guide Flex evaluation - The wire guide should show no signs of defects or damage, including flaking or material loss, when subjected to repeat flexing. Test results met predetermined criteria.
- Wire Guide Tensile Evaluation – Test articles must demonstrate Per the standard, minimum tensile strength for wire guides with having a diameter greater than or equal to 0.55 mm but less than 0.75 mm should have a peak load to failure greater than or equal to 5 N, and wire guides with diameters greater than 0.75 mm should have a peak load to failure greater than 10 N. The standard does not specify tensile strength for wire guide diameters less than 0.55 mm and requires the values to determined based on the risk assessment. Test results met predetermined criteria.
Biocompatibility - Per ISO 10993-1, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, thrombogenicity, material-mediated pyrogenicity, and hemocompatibility were performed to ensure the biocompatibility of the subject device set. Test results indicated that all materials are biocompatible.

**Conclusion:**

The results of these tests show that the Peel-Away® Introducer Sets meet the design input requirements based on the intended use. Further, these results support the conclusion that the Peel-Away® Introducer Sets do not raise new questions of safety or effectiveness and support a determination of substantial equivalence.