



May 29, 2019

Cook Incorporated
Johnathan Liu
Regulatory Affairs Manager
750 Daniels Way
Bloomington, IN 47404

Re: K182403
Trade/Device Name: Peel-Away® Introducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Dated: April 15, 2019
Received: April 16, 2019

Dear Johnathan Liu:

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,

for
Glenn B. Bell, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182403

Device Name

Peel-Away Introducer

Indications for Use (Describe)

The Peel-Away Introducer is intended to be used to establish a conduit during endoscopic urological procedures (e.g. nephrostomy, cystoscopy, ureteroscopy, etc.) facilitating the passage of endoscopes and other instruments into the urinary tract.

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

Peel-Away® Introducer
21 CFR §807.92
Date Prepared: April 15, 2019

Submitted By:

Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Primary Contact: Carly Powell
Secondary Contact: Paul Meyer
Email: regsubmissions@cookmedical.com
Contact Phone Number: (812) 335-3575 x104509
Contact Fax Number: (812) 332-0281

Device Information:

Trade Name: **Peel-Away® Introducer**
Common or Usual Name: Endoscopic Access Overtube, Gastroenterology-Urology
Classification Name: Endoscope and accessories
Regulation Number: 21 CFR §876.1500
Product Code: FED
Regulatory Class: II
Classification Panel: Gastroenterology/Urology

Predicate Devices:

The Cook Peel-Away® Introducer is substantially equivalent to the following devices:

- Flexor® Ureteral Access Sheath (K172217, Cook Inc.) cleared on Dec. 13, 2017.
- Vari-Pass™ Adjustable Length Access Sheath (K123170, Olympus Surgical Technologies America) cleared on Feb. 4, 2013.

Device Description:

The subject device, Peel-Away Introducer, consists of an inner dilator and outer peel-away sheath. The outer sheath fits over the inner dilator and has dual knobs allowing the sheath, manufactured from radiopaque polytetrafluoroethylene (PTFE), to be peeled back and removed. The sheath is manufactured with a length of 32 centimeters. The dilator has an outside diameter of 9, 10, or 12 French, and has a length of 37 centimeters. The 10 French dilator is manufactured from radiopaque polyethylene, while the 9 and 12 French dilators are manufactured from ethylene-vinyl acetate (EVA). The dilator is also tapered 1.2 to 1.5 centimeters from the distal end, depending on its outer diameter, and has a proximal hub composed of polyethylene. The Peel-Away Introducer is supplied sterile and intended for one-time use.

Indications for Use:

The Peel-Away Introducer is intended to be used to establish a conduit during endoscopic urological procedures (e.g. nephrostomy, cystoscopy, ureteroscopy, etc.) facilitating the passage of endoscopes and other instruments into the urinary tract.

Comparison to Predicate Device:

The Peel-Away[®] Introducer is substantially equivalent to the primary predicate device, Flexor Ureteral Access Sheath (K172217), and the secondary predicate device, Gyrus ACMI Vari-Pass Adjustable Length Access Sheath (K123170). The subject device has the same general intended use and principles of operation as the predicate devices. The differences in indications for use, sheath technology, materials, and dimensions between the subject device and the predicate devices do not raise different questions of safety and/or effectiveness.

Technological Characteristics:

The subject device Peel-Away Introducer 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:

Performance:

- Tensile (Time-Zero and Aged)
 - Dilator Shaft
 - Dilator Shaft-to-Hub
 - Peel-Away Sheath
- Peel Force (Time-Zero and Aged)
 - Peel-Away Sheath
- Rollback (Time-Zero and Aged)
- Compatibility (Time-Zero and Aged)
- Radiopacity
- Packaging
- Sterility

Biocompatibility Testing:

- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, and hemocompatibility were performed to ensure the biocompatibility of the subject device set.

Conclusion:

The results of these tests confirm that the Peel-Away Introducer meets the design input requirements based on the intended use and support the conclusion that this device does not raise different questions of safety and/or effectiveness as compared to the predicate device. The submitted information supports the determination that the subject device is substantially equivalent to the predicate devices, Flexor Ureteral Access Sheath (K172217) and Vari-Pass Variable Length Access Sheath (K123170).