October 30, 2018

Cook Incorporated
Carly Powell
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K182066
Trade/Device Name: O'Brien Suprapubic Peel-Away Access Set,
Cook® SP Tube Introducer Set
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOB
Dated: July 31, 2018
Received: August 1, 2018

Dear Carly Powell:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Timothy Martin -S
2018.10.30 17:45:00 -04'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K182066

Device Name

O'Brien Suprapubic Peel-Away Access Set

Cook® SP Tube Introducer Set

Indications for Use *(Describe)*

The O'Brien Suprapubic Peel-Away Access Set is used for introducing a drainage catheter suprapubically into the bladder.

The Cook® SP Tube Introducer Set is used for introducing a drainage catheter suprapubically into the bladder.

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.

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2.0 510(k) Summary

O'Brien Suprapubic Peel-Away Access Set
Cook SP Tube Introducer Set
21 CFR §807.5050
Date Prepared: July 31, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Carly Powell
Secondary Contact:	Karthik Pillai, Ph.D
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104913
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Names:	**O'Brien Suprapubic Peel-Away Access Set** **Cook SP Tube Introducer Set**
Common Name:	Catheter, Suprapubic (And Accessories)
Classification Name:	Suprapubic Urological Catheter and Accessories
Regulation:	21 CFR §876.5090
Product Code:	KOB
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Devices:

The O'Brien Suprapubic Peel-Away Access Set and the Cook SP Tube Introducer Set are substantially equivalent to the following devices:

- Suprapubic Catheter and Introducer Set cleared under K132890

Table 2.0-1 Comparison Table

	Predicate Device	Subject Device
	Suprapubic Catheter and Introducer Set (K132890)	**O'Brien Suprapubic Peel-Away Access Set**
Manufacturer	MediPlus Ltd.	Cook Inc.
Regulation	876.5090	Identical
Product Code	KOB [Catheter, Suprapubic (And Accessories)]	Identical
Classification	II	Identical
Indications for Use	The Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder. For use no greater than 29 days.	Used for introducing a drainage catheter suprapubically into the bladder.
Set Components	Syringe, scalpel, 18 gauge needle, peel-away sheath, dilator, and guidewire, Foley Catheter	Peel-away sheath, dilator, wire guide, trocar needle

Table 2.0-2 Comparison Table

	Predicate Device	Subject Device
	Suprapubic Catheter and Introducer Set (K132890)	**Cook SP Tube Introducer Set**
Manufacturer	MediPlus Ltd.	Cook, Inc.
Regulation	876.5090	Identical
Product Code	KOB [Catheter, Suprapubic (And Accessories)]	Identical
Classification	II	Identical
Indications for Use	The Suprapubic Catheter and Introducer Set is indicated for drainage of the bladder through a needle puncture or stab wound over the bladder. For use no greater than 29 days.	Used for introducing a drainage catheter suprapubically into the bladder.
Set Components	Syringe, scalpel, 18 gauge needle, peel-away sheath, dilator, and guidewire, Foley Catheter	Peel-away sheath, dilators, wire guide, trocar needle

Device Description:

The O'Brien Suprapubic Peel-Away Access Set includes a peel-away sheath, dilator, trocar needle and wire guide. The peel-away sheath is available in even-numbered French sizes ranging from 16.0 to 20.0 and measures 22 centimeters in length. Dual knobs allow the sheath, manufactured from thick wall radiopaque polytetrafluoroethylene material, to be peeled back and removed.

The Cook SP Tube Introducer Set is comprised of a 20 Fr sheath which is 15 cm in length, an introducer that fits within this sheath, two dilators, a wire guide and needle.

Intended Use:

The O'Brien Suprapubic Peel-Away Access Set and Cook SP Tube Introducer Set are intended for introducing a drainage catheter suprapubically into the bladder.

Comparison to Predicate:

The subject and predicate device, Suprapubic Catheter Introducer Set, are substantially equivalent in that these devices are similar in indications for use and method of placement. Additionally, the subject devices have a similar design and technological characteristics as the predicate devices. The differences between the subject devices and the predicate devices include, the absence of a drainage catheter in the set, materials, and dimensions. Characteristics of the subject devices that differ from the predicate devices are supported by testing and do not raise any new questions of safety and effectiveness.

Performance Data:

The subject devices, O'Brien Suprapubic Peel-Away Access Set and the Cook SP Tube Introducer Set, were 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:

- Radiopacity Testing
- Peel-Away Shaft Tensile Test
- Dilator Shaft Tensile Test
- Peel Force
- Rollback Testing
- Dilator Hub-to-Shaft Tensile Test
- Compatibility Testing
- Biocompatibility – Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, and Acute Systemic Toxicity
- Sterilization
- Package integrity and stability
- Shelf-life

All predetermined acceptance criteria were met.

Conclusion:

The data included in this submission indicate that the subject devices do not raise new questions of safety or effectiveness compared to the predicate device, the Suprapubic Catheter and Introducer Set (K132890), which supports a determination of substantial equivalence.