



December 13, 2017

Cook Incorporated
Andrew Breidenbach, Ph.D., RAC
Regulatory Scientist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K172217
Trade/Device Name: Flexor® Ureteral Access Sheath and
Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: November 21, 2017
Received: November 22, 2017

Dear Andrew Breidenbach:

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,


Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K172217

Device Name

Flexor® Ureteral Access Sheath

Indications for Use (Describe)

The Flexor® Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract. Thirteen (13) cm length is intended for use in pediatric patients two (2) years of age and over.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K172217

Device Name

Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath

Indications for Use (Describe)

The Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures, 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)

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510(k) SUMMARY

**Flexor® Ureteral Access Sheath and
Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath
21 CFR §807.92**

Date Prepared: July 19, 2017

Submitted By:

Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact: Andrew Breidenbach
Email: regsubmissions@cookmedical.com
Contact Phone Number: (812) 335-3575 x105147
Contact Fax Number: (812) 332-0281

Device Information:

Trade Name: **Flexor® Ureteral Access Sheath and
Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath**
Common Name: Endoscopic Access Overtube, Gastroenterology-Urology
Classification Name: Endoscope and accessories
Regulation: 21 CFR 876.1500
Product Code: FED
Device Class: II
Classification Panel: Gastroenterology/Urology

Predicate Devices:

- The Cook® Pediatric Flexor Ureteral Access Sheath (K043418) is intended for use in establishing a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. The Cook® Pediatric Flexor Ureteral Access Sheath is intended for Pediatric Use in patients two years of age and older.
- The Coloplast A/S Re-Trace Ureteral Access Sheath (K140523) is intended to be used to establish a continuous conduit during urological endoscopic procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

Device Description:

The Flexor® Ureteral Access Sheath and Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath are available with outside diameters ranging from 9.5 to 14 French and lengths ranging from 13 to 55 centimeters. These devices are available in a single lumen configuration and include a sheath and a dilator. The dilator component includes a tapered and a hydrophilically coated distal tip. In addition, the Flexor Parallel Rapid Release Ureteral Access Sheath also includes a skive and slit in the tip of the dilator which allows the wire guide to run outside and parallel to the sheath and to be separated from the sheath while inside the body to serve as a safety wire. Both Ureteral Access Sheaths are constructed of Nylon with a 304 Stainless Steel coil and a TFE liner. The dilator component is constructed of polyethylene. Table 2-1 presents the sizes of devices that will be available.

Table 1. Sizes of the Flexor Ureteral Access Sheath (FUAS) and Flexor Parallel Rapid Release Ureteral Access Sheath (FPRR) to be available.

		Inner Diameter (Fr)			
		9.5	10.7	12.0	14.0
Length (cm)	13	FUAS*/-----	FUAS*/-----	FUAS*/-----	----- / -----
	20	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR
	28	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR
	35	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR
	45	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR
	55	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR	FUAS/ FPRR

* Only these 3 configurations of the Flexor Ureteral Access Sheath (FUAS) are indicated for pediatric patients. The Flexor Parallel Rapid Release Ureteral Access Sheath (FPRR) does not have sizes for pediatric use.

The Flexor Ureteral Access Sheath and Flexor Parallel Rapid Release Ureteral Access Sheath are supplied sterile and intended for one-time use.

Intended Use:

The **Flexor® Ureteral Access Sheath** is used to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract. Thirteen (13) cm length is intended for use in pediatric patients two (2) years of age and over.

The **Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath** is used to establish a conduit during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the urinary tract.

Comparison to Predicate Device:

The subject Flexor Ureteral Access Sheath and the Flexor Parallel Rapid Release Ureteral Access Sheath are substantially equivalent to the Cook® Pediatric Flexor Ureteral Access Sheath (Cook Incorporated, K043418) with regard to technological characteristics, materials, intended use, and methods of construction. In addition, the Flexor Parallel Rapid Release Ureteral Access Sheath is substantially equivalent to the Coloplast A/S Re-Trace Ureteral Access Sheath (K140523) with respect to technological characteristics, intended use, and methods of construction.

The Flexor® Ureteral Access Sheath and Flexor Parallel Rapid Release Ureteral Access Sheath are almost identical to the Cook Pediatric Flexor Ureteral Access Sheath (K043418) and so it functions as the primary predicate. The secondary predicate, the Coloplast A/S Re-Trace Ureteral Access Sheath (K140523), has additional lengths not present in the primary predicate as well as a 14 Fr diameter to allow for use in adults. The secondary predicate also provides the wire guide rapid release function, which allows the wire guide to be released *in situ* from the dilator to serve as a safety wire. Table 2-2 provides a comparison of the subject devices with the predicates.

Table 2. Comparison to predicates.

	PRIMARY PREDICATE DEVICE (1)	SECONDARY PREDICATE DEVICE (2)	SUBJECT DEVICES
	Cook® Pediatric Flexor Ureteral Access Sheath (K043418)	Coloplast A/S Re-Trace Ureteral Access Sheath (K140523)	Flexor® Ureteral Access Sheath AND Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath
Manufacturer	Cook Incorporated	Coloplast A/S	Cook Incorporated
Regulation	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	Identical to Predicate 1 & 2
Product Code	FED Endoscopic Access Overtube, Gastroenterology-Urology	FED Endoscopic Access Overtube, Gastroenterology-Urology	Identical to Predicate 1 & 2
Classification	II	II	Identical to Predicate 1 & 2
Indications for Use	Used to establish a conduit during endoscopic urological procedures to facilitate the passage of endoscopes and other instruments into the urinary tract. The Cook® Pediatric Flexor Ureteral Access Sheath is intended for Pediatric Use in patients two years of age and older.	Used to establish a continuous conduit during urological endoscopic procedures facilitating the passage of endoscopes and other instruments into the urinary tract.	Used to establish a conduit during endoscopic urological procedures to facilitate the passage of endoscopes and other instruments into the urinary tract. The 13 cm length Flexor® Ureteral Access Sheaths are intended for Pediatric Use in patients two years of age and older.
Dilator Material	Polyethylene	Outer Surface: (PVC) Radiopaque Polyvinyl Chloride Inner Surface: (PTFE) Polytetrafluoroethylene	Identical to Predicate 1
Hydrophilic Coating	Yes	Yes	Identical to Predicate 1
Sheath Material	Nylon 12 with 304 Stainless Steel Coil and PTFE liner	Polyether Block Amide (PEBA)	Identical to Predicate 1
Sheath Length (cm)	13	35-45	13*, 20, 28, 35, 45, 55
Sheath ID (French)	9.5, 12.0	12, 14	9.5*, 10.7*, 12.0*, 14.0
Working Channels	1 or 2	1	1
Wire Guide Release Feature	No	Yes	Yes, on Flexor Parallel Rapid Release Ureteral Access Sheath model

* The 13-cm length sheaths will only be available in 9.5 Fr, 10.7 Fr and 12.0 Fr IDs of the Flexor® Ureteral Access Sheath to serve the pediatric indication. The Flexor Parallel Rapid Release Ureteral Access Sheath will not be available in the 13-cm length.

Technological Characteristics:

The following tests were performed to demonstrate that the Flexor® Ureteral Access Sheath and Flexor® Parallel™ Rapid Release™ Ureteral Access Sheath met applicable design and performance requirements and support a determination of substantial equivalence.

Device specific testing requirements - Mechanical

- Dilator Buckling Force
- Sheath Tensile Strength
- Dilator Tensile Strength
- Sheath to Hub Tensile Strength
- Dilator to Hub Tensile Strength
- Dilator Tip Tensile Strength

Device specific testing requirements – Functional

- Lubricity Length
- Kink Resistance
- Bench Testing/Simulated Use
- Tip Flexibility
- Sheath Inner Lumen Passability (Resistance)
- Sheath Inner Lumen Durability

Device specific testing requirements – Radiopacity

- Radiopacity

General testing requirements

- Biocompatibility for devices with ≤ 24 hour Mucosal Membrane Contact
 - Cytotoxicity
 - Sensitization
 - Irritation or Intracutaneous Reactivity
- Sterilization
 - Sterility Testing
 - Residuals from ETO sterilization
- Distribution Testing
 - Packaging/Transportation Testing
- Shelf Life/Stability

Conclusion:

The results of these tests demonstrate that the Flexor Ureteral Access Sheath and the Flexor Parallel Rapid Release Ureteral Access Sheath meet the design input requirements based on the intended use. They support the conclusion that these devices do not raise new questions of safety or effectiveness and are substantially equivalent to the Cook Pediatric Flexor Ureteral Access Sheath (K043418) and the Coloplast A/S Re-Trace Ureteral Access Sheath (K140523).