April 16, 2018

Cook Incorporated
Erum B. Nasir
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, IN 47402

Re: K171603
Trade/Device Name: Cope Nephroureterostomy Stent and Amplatz Ureteral Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: March 6, 2018
Received: March 7, 2018

Dear Erum B. Nasir:

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. 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); 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

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)*
K171603

Device Name
Cope Nephroureterostomy Stent

Indications for Use *(Describe)*
The Cope Nephroureterostomy Stent is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent. The Cope Nephroureterostomy Stents are not intended to remain indwelling more than 90 days.

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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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
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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)*
K171603

Device Name
Amplatz Ureteral Stent Set

Indications for Use *(Describe)*
The Amplatz Ureteral Stent Set is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally. The Amplatz Ureteral Stents are not intended to remain indwelling more than 180 days.

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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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

K171603
Cope Nephroureterostomy Stent and the Amplatz Ureteral Stent Set
21 CFR, §876.4620
Date Prepared: April 13, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Erum B. Nasir
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102607
Contact Fax Number:	(812) 332-0281

Proposed Device:

Trade Name:	Cope Nephroureterostomy Stent and the Amplatz Ureteral Stent Set
Regulation Number:	21 CFR §876.4620
Regulation Name:	Ureteral stent
Regulatory Class:	Class II
Product Code:	FAD
Common Name:	stent, ureteral
Classification Panel:	Gastroenterology/Urology

Predicate Devices:

Expel™ Nephroureteral Drainage Stent with Twist-Loc Hub System and the Expel™ Ureteral Drainage Stent System (K141344), cleared for market by FDA on October 17, 2014, and the Percuflex Nephroureteral Stent (K924608), cleared for market on January 26, 1994.

Device Description:

The Cope Nephroureterostomy Stent is an internal/external draining stent consisting of double pigtails (proximal pigtail in the renal pelvis and distal pigtail in the bladder). The Cope nephroureterostomy stent is designed with a Mac-Loc locking mechanism. This locking mechanism consists of an ABS body, stainless steel pin, and valox lever with a 30 to 40 cm nylon filament (suture). The nylon monofilament runs between the Mac-

Loc® cap and extends through a 6.5 cm segment in the stent shaft corresponding with the positioning of the proximal loop and enters and exits through two puncture holes in the stent. The Cope Nephroureterostomy stents are manufactured using polyether-urethane material and are designed with sideports. The stents are available in diameters ranging from 8.5 Fr to 14.0 Fr and working lengths ranging from 10 to 32 cm. The device includes a stiffening cannula that aids in the placement of the stent and also includes a catheter securement device. All proposed devices are supplied sterile for single use.

The Amplatz Ureteral Stent Set is an internal draining stent that consists of double pigtails, with the proximal pigtail forming in the renal pelvis and the distal pigtail forming in the bladder. The set also includes a stent positioner with stent introducer catheter and loading stylet. The Amplatz Stent is composed of polyether-urethane material and designed with sideports that are located on the proximal and distal pigtails. The stents are available in diameters of 8.5 Fr or 10.2 Fr and length ranging from 10 to 30 cm. The distal end of the Amplatz Stent has a hydrophilic coating. A suture is looped through the most proximal drainage hole which allows for stent adjustment or removal during placement, and the suture is removed once placement is complete. All proposed devices are supplied sterile for single use.

Intended Use:

The Cope Nephroureterostomy Stent is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent. The Cope Nephroureterostomy Stents are not intended to remain indwelling more than 90 days.

The Amplatz Ureteral Stent Set is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally. The Amplatz Ureteral Stents are not intended to remain indwelling more than 180 days.

Comparison to Predicates:

The Cope Nephroureterostomy Stents and predicate devices, the Expel™ Nephroureteral Drainage Stent with Twist-Loc Hub System (K141344) and the Percuflex™ Nephroureteral Stent (K924608), have similar design and intended use. Additionally, the subject devices have the same technological characteristics and methods of placement as those of the predicate device. The differences between the subject device and the predicate device include the dimensions, materials, and indwell time.

The Amplatz Ureteral Stent Set and the predicate device, the Expel™ Ureteral Drainage Stent System (K141344), have similar design and intended use. Additionally, the subject devices have the same technological characteristics and methods of placement as those of the predicate device. The differences between the subject device and the predicate device include the dimensions, materials, and indwell time.

The substantial equivalence comparison with the predicates of each subject device is provided in Table 1 and Table 2.

Table 1 Substantial Equivalence Table – Cope Nephroureterostomy Stent

Device		PRIMARY PREDICATE Expel™ Nephroureteral Drainage Stent With Twist - Loc Hub System K141344	SECONDARY PREDICATE Percuflex Nephroureteral Stent K924608	Cope Nephroureterostomy Stent (Subject device)
Regulation Number		876.4620	876.4620	Identical
Regulation Description		Ureteral Stent	Ureteral Stent	Identical
Product Code		FAD	FAD	Identical
Classification		Class II	Class II	Identical
Intended Use		The Expel Nephroureteral Stents are delivered percutaneously and are intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.	The Percuflex Nephroureteral Stent is intended for use in Percutaneous Drainage to establish internal drainage from the uteropelvic junction to the bladder while maintaining external access to the stent.	The Cope Nephroureterostomy Stent is delivered percutaneously and is intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent. The Cope Nephroureterostomy Stents are not intended to remain indwelling more than 90 days.
Stent	**Stent Size (Fr)**	8.3, 10.3	8, 10	8.5, 10.2, 12.0, 14,0
	Stent Length (cm)	22, 28	22, 24, 26, 28	20, 22, 24, 26, 28
	Stent Material	Flexithane™ (Polyurethane)	Percuflex (proprietary olefinic block copolymer)	Polyether-Urethane
	Marker Bands	Unknown	Unknown	Platinum/Iridium
	Stent Coating (Distal portion only)	Unknown hydrophilic coating	Unknown hydrophilic coating	Slip-coat
	Suture Material	Unknown	Unknown	Monofilament - Nylon
	Sideports	Yes	Yes	Yes
	Pigtails	Double Pigtail (proximal pigtail in the renal pelvis and distal pigtail in the bladder)	Double Pigtail (proximal pigtail in the renal pelvis and distal pigtail in the bladder)	Identical
	Pigtail Curl Diameter	Unknown	Unknown	2.0 cm – 3.0 cm
	Pigtail Curl Arcs	360°, both ends	Unknown	Identical to Primary Predicate

Table 1 Substantial Equivalence Table – Cope Nephroureterostomy Stent (contd)

Device		PRIMARY PREDICATE Expel™ Nephroureteral Drainage Stent With Twist - Loc Hub System K141344	SECONDARY PREDICATE Percuflex Nephroureteral Stent K924608	Cope Nephroureterostomy Stent (Subject device)
Stent	**End Hole Side (inch)**	Unknown	Unknown	0.038
	Locking Mechanism	Loc Hub System	Locking Hub	Mac-Loc
Flexible Stiffening Cannula	**Shaft Material**	Unknown	Unknown	Nylon
Securement Device		Unknown	Unknown	Yes
Indwelling Time		30 Days	90 Days	90 Days
Sterilization method		Unknown	Unknown	Ethylene oxide
Sterility level		Unknown	Unknown	10^{-6}

Table 2 Substantial Equivalence Table - Amplatz Ureteral Stent Set

Device		Expel™ Ureteral Drainage Stent System - Predicate K141344	Amplatz Ureteral Stent Set - Subject Device
Regulation Number		876.4620	Identical
Regulation Description		Ureteral Stent	Identical
Product Code		FAD	Identical
Classification		Class II	Identical
Intended Use		The Expel Ureteral Stent System is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.	The Amplatz Ureteral Stent Set is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally. The Amplatz Ureteral Stents are not intended to remain indwelling more than 180 days.
Stent	**Stent Size (Fr)**	6.3, 8.3, 10.3	8.5, 10.2
	Stent Working Length (cm)	12, 28	10.0-30.0
	Stent material	Flexithane™ (Polyurethane)	Polyether-Urethane
	Stent Coating (Distal portion only)	Unknown Hydrophilic Coating	Slip-Coat
	Pigtails	Pigtail on each end (proximal pigtail in the renal pelvis and distal pigtail in the bladder)	Identical
	Pigtail Curl Diameter	Unknown	2.0 cm – 3.0 cm
	Pigtail Curl Arcs	360°, both ends	360°, both ends
	Sideport	Yes	Yes
	Marker Bands	Unknown	Platinum/Iridium
	Suture	Unknown	Monofilament - Nylon
Stent Positioner	**Cap Material**	Unknown	Nylon
	Y-Fitting Material	Unknown	Acetal
	Hub	Unknown	Nylon
	Shaft Material	Unknown	Vinyl
Introducer Catheter	**Material**	Unknown	Polytetrafluoroethylene
	Marker Band	Unknown	Platinum/Iridium
Loading Stylet	**Cannula Material**	Unknown	Stainless Steel
	Hub Material	Unknown	Polypropylene
Indwelling Time		30 Days	180 Days
Sterilization method		Unknown	Ethylene oxide
Sterility level		Unknown	10^{-6}

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements:

- Dimensional and Compatibility - (stent, flexible stiffener, rigid stiffener, wire guide) - Testing in accordance with JIS T 3270 showed that dimensions and component compatibility was adequate for clinical use.
- Tensile Testing (stent, introducer catheter, loading stylet, stent positioner, flexible stiffener) – Testing in accordance with BS EN 1617 showed that the peak load value was greater than or equal to the predetermined acceptance criterion.
- Curl Retention Strength Testing – Testing in accordance with ASTM F 1828-97 showed that the retention force greater than or equal to the predetermined acceptance criterion.
- Liquid leakage (for Nephroureterostomy stent) – Testing in accordance with BS EN 1615 showed that the connection did not leak.
- Flow rate Testing – Testing in accordance with BS EN 1618 showed that the minimum average flow rate greater than or equal to the predetermined acceptance criterion.
- Radiopacity – Testing following the method described in ASTM F6540-12, "Standard Test Methods for Determining Radiopacity for Medical Use" showed the radiopacity of the Nephroureterostomy Stent was determined to be non-inferior to the radiopacity of the selected comparative device.
- Kink Radius Testing – Testing was performed for characterization only
- Lubricity Testing – Testing met predetermined peak force acceptance criterion.
- MRI Testing – Testing in accordance with ASTM F2503 showed that the Cope Nephroureterostomy Stent and the Amplatz Ureteral Stent Set are MR Conditional.
- Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, subchronic toxicity, material mediated pyrogenicity, implantation, and genotoxicity demonstrated that the devices are biocompatible.

For these tests, all pre-determined acceptance criteria were met. The results of these tests showed that the subject devices met the design input requirements based on the intended

use, and support the conclusion that these devices are substantially equivalent to the predicate devices.