July 16, 2019

Cook Incorporated
Ian Herrman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K183051
Trade/Device Name: Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set
Kaye Nephrostomy Tamponade Balloon Catheter
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LJE
Dated: June 10, 2019
Received: June 11, 2019

Dear Ian Herrman:

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K183051

Device Name
Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set

Kaye Nephrostomy Tamponade Balloon Catheter Set

Indications for Use *(Describe)*

The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set is used for nephrostomy drainage, ureteral drainage, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.

The Kaye Nephrostomy Tamponade Balloon Catheter Set is used for nephrostomy drainage, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.

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
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) Summary

K183051
Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set
21 CFR §807.92
Date Prepared: July 16, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Ian Herrman
Secondary Contact:	Karthik Pillai, Ph.D.
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Phone Number:	(812) 335-3575 x104034
Fax Number	(812) 332-0281

Device Information:

Submission:	Traditional 510(k) Premarket Notification
Trade/Device Name:	Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set Kaye Nephrostomy Tamponade Balloon Catheter Set
Device Common Name:	Catheter, Nephrostomy
Regulation Number:	N/A
Regulation Name:	N/A
Classification Product Code:	LJE
Device Class:	Unclassified
Review Panel:	Gastroenterology/Urology

Predicate Devices:

- Malecot-Nephrostomy Tamponade Catheter, Cook Incorporated, K915209
- Expel™ Nephroureteral Stent System with Twist-Loc Hub, Boston Scientific, K141344

Device Description:

The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set is comprised of a balloon catheter, ureteral stent, flexible stylet, Y-connecting tube and syringe. The

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

balloon catheter can be sold separately with the stylet and syringe. The radiopaque balloon catheter has an outer diameter of 14.0 French and a tip diameter of 17.0 French, with a working length of 25 centimeters. The clear polyethylene balloon measures 15 centimeters in length and has an inflated diameter of 12 millimeters. The flexible stylet is 8.5 French and is manufactured from polyurethane material. The flexible stylet, designed to be inserted through the proximal end of the balloon catheter, extends 2 millimeters from the balloon catheter tip when assembled. The stent is manufactured from radiopaque polyurethane with an outer diameter of 5.0 French and a length of 75 centimeters. The stent is designed with two adjustable and removable adapters located at the proximal end of the stent. The Y-connecting tube is made of non-radiopaque polyvinylchloride material with an outer diameter of 14.0 French, and a length of 30 centimeters. A 10 mL Luer-lock syringe is also provided in the set and is used to inflate the balloon through the inflation check valve.

The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set is supplied sterile in a Tyvek peel open pouch and labeled with a three-year shelf life. The subject device has a maximum indwell time of 96 hours (4 days) for the stent and 48 hours (2 days) for the balloon catheter and is labeled as a single-use device.

Intended Use:

The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set is used for nephrostomy drainage, ureteral drainage, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.

The set sold without the stent component has the following intended use:

The Kaye Nephrostomy Tamponade Balloon Catheter Set is used for nephrostomy drainage, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.

Comparison to Predicates:

The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set and the predicate devices, the Malecot-Nephrostomy Tamponade Catheter (K915209) and the Expel™ Nephroureteral Stent System with Twist-Loc Hub (K141344), are substantially equivalent in that these devices share similar indications for use, methods of operations and fundamental technological characteristics. The Malecot-Nephrostomy Tamponade Catheter (K915209) is the predicate specifically for the balloon catheter component of the subject device set. The Expel™ Nephroureteral Stent System with Twist-Loc Hub

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

(K141344) is the predicate specifically for stent component of the subject device set. Comparisons between each predicate and the corresponding subject device component are presented in the following tables.

Balloon Catheter and Stylet:

Device Characteristics	Predicate Device K915209 - Malecot-Nephrostomy Tamponade Catheter	Subject Device K183051 - Kaye Nephrostomy Tamponade Balloon Catheter	Comparison
Indications for Use	The Malecot-Nephrostomy Tamponade Catheter is used for nephrostomy drainage and low pressure dynamic tamponade to prevent hemorrhage following percutaneous stone removal.	Used for nephrostomy drainage, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.	The subject and the predicate device are both used for nephrostomy drainage, and dynamic tamponade to prevent hemorrhage following percutaneous stone removal. The slight difference in wording does not raise new questions of safety and effectiveness (S&E) as the balloons are labeled with the same max volume and pressure.
Placement Method	Percutaneous	Identical	Identical
Maximum Indwell Time	5 days	2 days (48 hours)	The subject device has a shorter maximum indwell time than the predicate. This shorter indwell time does not raise any new questions of S&E.
General Design	Balloon Catheter with stylet and syringe accessories	Identical	Identical
Materials	Balloon: Polyethylene Catheter Tubing: Polyethylene, non-radiopaque tubing	Balloon: Polyethylene Catheter Tubing: Ethylene-vinyl acetate copolymer, radiopaque	Material differences in these catheters do not raise new questions of S&E as demonstrated by biocompatibility and performance testing.
Balloon Length	15 cm	Identical	Identical
Balloon Diameter	12 mm	Identical	Identical
Max inflation pressure	40 psi	Identical	Identical
Catheter Length	25.7 cm	25 cm	The slight difference in length does not raise questions of S&E.
Catheter Tip	16 Fr malecot tip	17 Fr dual sideport tip	The difference in tip diameter and drainage opening type does not raise different questions of S&E
Catheter Shaft Diameter	16 Fr	14 Fr	The subject device catheter shaft has a smaller outer diameter than the predicate device. Performance testing indicates the difference in outer diameter raises no new questions of S&E.

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Regarding technological characteristics, the subject and predicate balloon catheter (K141344) devices have similarities in their general designs. However, differences do exist as described in the table above (e.g., tip drainage design, dimensions, materials, etc.) The differences identified do not raise different questions of safety and/or effectiveness as compared to the predicate device, as stated in the table.

Stent:

Device Characteristics	Predicate Device K141344 - Expel™ Nephroureteral Stent System with Twist-Loc Hub	Subject Device K183051 - Kaye Nephrostomy Tamponade Balloon Catheter Stent	Comparison
Indications for 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.	Used for nephrostomy drainage, **ureteral drainage**, and dynamic tamponade to prevent hemorrhage in nephrolithotomy and percutaneous stone removal procedures.	The subject device has a different indication for use statement compared to predicate K141344. However, the stent included in the subject device has the same intended use as the predicate K141344, which is internal drainage to the bladder and external drainage from the ureteropelvic junction while maintaining external access to the stent.
Maximum Indwell Time	30 days	4 days (96 hours)	The subject device stent component has a 4 day maximum indwell time which is shorter than that of the predicate. Because the subject device maximum indwell time falls within that of the predicate device no new questions of S&E are raised.
General Design	Single lumen nephroureteral stent with distal and proximal retention pigtails with sideports	Single lumen straight nephroureteral stent with sideports.	The predicate and subject device are similar in general design. The main difference in design is that the predicate device has pigtails in the bladder and ureteropelvic junction for retention. In the subject, device retention is assured either through connection to the balloon catheter through the proximal adapter and/or anchoring the device to the patient. Thus, the difference in design does not raise new questions of S&E.
Materials	Radiopaque Flexithane	Radiopaque Polyurethane	Material differences between the predicate and subject devices do not raise new questions of S&E as demonstrated by biocompatibility and performance testing.
Stent Length	Total: 65 Working length: 22-28 cm	Total: 75 Working length: 33 cm (adjustable)	The total length of the predicate stent is 65 cm with a working length of 22-28 cm. The total length of the subject device is 75cm with a

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Device Characteristics	Predicate Device K141344 - Expel™ Nephroureteral Stent System with Twist-Loc Hub	Subject Device K183051 - Kaye Nephrostomy Tamponade Balloon Catheter Stent	Comparison
			working length adjustable up to 33 cm. The total length and working length of the subject device stent encompasses the predicate stent and does not generate any new questions of S&E.
Stent Diameter	8.3 and 10.3 Fr	5 Fr	The subject device stent has a smaller outer diameter compared to the predicate device stent. The smaller stent outer diameter ensures that the predicate can be used in the same patient anatomy as the predicate. Performance testing has demonstrated that this difference does not generate any new questions of S&E.

As shown above, the indications for use statement of the subject device set including the stent component is not identical to the predicate device; however, the differences do not represent a new intended use as both the predicate device stent and subject device stent have the same intended use.

Regarding the technological characteristics, the subject and predicate devices have similarities in their general designs. However, differences do exist as described in the table above (e.g., dimensions, materials, indwell time, etc.) The differences identified do not raise different questions of safety and effectiveness as compared to the predicate device as stated in the table.

Technological Characteristics:

The following tests were performed to demonstrate that The Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set met applicable design and performance requirements and support a determination of substantial equivalence:

1. Biocompatibility
2. Sterility
3. Packaging: Distribution and Stability
4. Shelf-life
5. Balloon Catheter:
    a. Compatibility

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

   b. Dimensional Verification
   c. Balloon Inflation Volume
   d. Balloon Catheter Rated Burst Pressure
   e. Tensile Test
   f. Radiopacity
6. Stent:
   a. Compatibility
   b. Dimensional Verification
   c. Tensile Test
   d. Flow Rate Test
   e. Kink and Lumen Patency
   f. Radiopacity
7. Stylet:
   a. Compatibility
   b. Dimensional Verification
   c. Tensile Test
8. Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set:
   a. Liquid Leakage and Gravity Flow

Conclusion:

The results of these tests provide reasonable assurance that the Kaye Nephrostomy Tamponade Balloon Catheter and Stent Set will perform as intended. The subject device does not raise different questions of safety and/or effectiveness as compared to the predicate devices. In conclusion, the results of these tests support a determination of substantial equivalence to the predicate devices.