March 10, 2022

Coloplast Corp
Angela Kilian
Head of Regulatory, North America
1601 West River Road North
Minneapolis, MN 55411

Re: K211911
Trade/Device Name: Kolibri® Percutaneous Nephrostomy Catheters, Kolibri® Percutaneous Nephrostomy Kits, Kolibri® Direct Puncture Sets
Regulatory Class: Unclassified
Product Code: LJE
Dated: February 11, 2022
Received: February 11, 2022

Dear Angela Kilian:

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,

Jessica K. Nguyen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211911

Device Name
Kolibri® Percutaneous Nephrostomy Catheters, Kolibri® Percutaneous Nephrostomy Kits , Kolibri® Direct Puncture Sets

Indications for Use *(Describe)*
For short-term (up to 30 days) percutaneous drainage of the upper urinary tract in adult patients.

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

1. Submitter Information

510 (k) submitter	Coloplast A/S
Address	Holtedam 1 3050 Humlebaek Denmark
Contact Person	Angela Kilian Head of Regulatory Affairs, North America 1601 West River Road, Minneapolis, MN 55411 Office : 612-422-7956 Email : usaby@coloplast.com
Preparation date	March 09, 2022

2. Device Name

Trade Name of the Device	Kolibri® Percutaneous Nephrostomy Catheters Kolibri® Percutaneous Nephrostomy Kits Kolibri® Direct Puncture Sets
Common Name	Percutaneous Nephrostomy Catheter
Classification Name	Unclassified
Classification Regulation	Unclassified
Device Class	Unclassified
Panel	Gastroenterology/Urology
Product Code	LJE

3. Predicate and Reference Devices

	Predicate Device	Reference Device
Owner	Cook Incorporated	Coloplast Corp
Trade Name of the Device	Universa Percutaneous Drainage Catheter	Vortek Double Loop Ureteral Stent
Classification Name	Unclassified	Stent, Ureteral
Regulation Classification	Unclassified	21 CFR 876.4620
Device Class	Unclassified	II
Panel	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FEW, KOB, LJE	FAD
510(k) Number	K140085	K180057

4. Device Description

Kolibri® Percutaneous Nephrostomy Catheters and Kits

The Kolibri® Percutaneous Nephrostomy Catheters are available in two configurations based on the tip configuration termed either J or Malecot. The distal end of the J catheter resembles a loop, and the distal end of the Malecot catheter has 4-wings which form an open basket to hold the catheter in place. J and Malecot catheters are single lumen catheters with outer diameters ranging from 6 Fr to 20 Fr. The J and Malecot catheters are manufactured from the material branded Vortek by Coloplast. The catheters are supplied either individually or as part of a kit. The following components are included depending on the specific configuration:

- Stylet
- Silicone sleeve
- Stopcock
- Female Luer
- Urine bag connector
- Guidewire (kits only)
- Dilator set(s) (kits only)
- Chiba needles (kits only)

The dilators, Chiba Needles, and guidewires are all packaged separately. The J and Malecot catheters are supplied sterile via ethylene oxide for single use.

Kolibri Direct Puncture Set

The Direct Puncture Set consists of an 8 Fr or 10 Fr J catheter with a silicone sleeve, stopcock, urine bag connector, transparent reinforced tube, stainless-steel trocar needle, and stainless-steel stylet. The Direct Puncture Set is supplied sterile via ethylene oxide for single use.

5. Indication For Use

For short-term (up to 30 days) percutaneous drainage of the upper urinary tract in adult patients.

6. Comparison of the Technological Characteristics with Predicate and Reference Devices

Device & Predicate Device(s):	K211911	K140085 (Predicate Device)	K180057(Reference Device)	
General Device Characteristics				
Indication For Use	For short-term (up to 30 days) percutaneous drainage of the upper urinary tract in adult patients	The Universa Loop/Malecot Drainage Catheter Set is intended to provide percutaneous urine drainage from the genitourinary system.	The double loop ureteral stents are used for: drainage of the upper urinary tract over fistulas or ureteral obstacles and for healing of the ureter	*Similar to the predicate*
Device Type	Catheter, Nephrostomy	Catheter, Nephrostomy	Stent, Ureteral	*Same as the*

	Product Codes: LJE	Product Codes: LJE	Product Code: FAD	*predicate Device*
Device Components	Kolibri® Percutaneous Nephrostomy Catheter includes either a J or Malecot catheter, and some combination of silicone sleeve, stopcock, Luer, urine bag connector and stylet in some models.	The Universa Percutaneous Drainage Catheter Sets available as a loop catheter or a Malecot catheter. Suprapubic sets includes drainage catheter, connecting tube, straightening stylets, trocar needle with obturator, hollow needle, wire guide, dilators, silicone retention disc with pull tie, or one-way stopcock.	The Vortek Double Loop Ureteral Stents are supplied in kits, which contain a double-loop ureteral stent, a steerable pusher or a non-steerable pusher with clamp and a guidewire.	*Similar to the predicate*
Catheter tube Material	Polyether block amide	Polyurethane	Polyether block amide	*Different from the predicate but similar to reference device*
Length	29 – 36 cm	15 – 30 cm	12 – 30 cm	*Different from the predicate*
Catheter French Size	06 Fr. to 14 Fr. (J) 8 Fr. to 20 Fr. (Malecot)	06 to 14 Fr. (Loop) 08 to 24 Fr. (Malecot)	CHF 4.8,6,7,8 FR.	*Similar to the predicate*
Tip Configuration	J and Malecot	Loop and Malecot	Double loop	*Similar to the predicate*
Duration of Use	up to 30 days and cumulative use up to 90 days	4 weeks	6 months	*Similar to the predicate*
Intended patient Population	Adults only	Adults only	Adults and pediatric (infants, and adolescents) population	*Similar to the predicate*

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject catheters, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. Performance Data

Below is a list of the tests that have been performed and successfully completed for the subject catheters:

- Biocompatibility testing according to ISO 10993-1:2018 and FDA Guidance “Use of International Standard ISO 10993-1” (2016)
- Ethylene oxide residual testing according to ISO 10993-7
- EO sterilization according to ISO 11135:2014
- Bacterial Endotoxins testing according to ANSI/AAMI ST72:2019 and USP <85>

The following list of bench testing was conducted on the subject catheters using established methods to determine the substantial equivalence with the predicate:

- Visual inspection
- Compatibility Testing
- Dimensional verification
- Flow Rate
- Loop strength
- Tensile testing including tip, body, loop, and connector/body junction.
- Simulated use
- Implant simulation
- Shelf Life/Expiration date

All predetermined acceptance criteria were met.

8. Conclusion

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.