February 25, 2021

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

Re: K201436
Trade/Device Name: Vortek® Single Loop Ureteral Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: February 22, 2021
Received: January 25, 2021

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. 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 801and Part 809); 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,

Sharon M. Andrews
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)*
K201436

Device Name

Vortek® Single Loop Ureteral Stent

Indications for Use *(Describe)*

Surgical indication:
The Vortek® Single Loop Ureteral Stent is intended for use in ureterostomy or vesical replacement in adult and pediatric (adolescents, children, and infants) patients requiring endourological procedure and /or short-term (less than 30 days) drainage of the upper urinary tract.

Endoscopic indication:
The Vortek® Single Loop Ureteral Stent is intended for short-term (less than 30 days) drainage of urine from the upper urinary tract over fistulas or ureteral obstacles in adult and pediatric (adolescents, children, and infants) 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.

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

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510(k) SUMMARY – K201436

I. SUBMITTER INFORMATION:

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: 612-422-7956 Email: usaby@coloplast.com
Name of Contact Person:	Angela Kilian Head of Regulatory Affairs, North America
Address/Contact:	1601 West River Road North Minneapolis, MN 55411
Date Prepared:	February 18, 2021

II. DEVICE CLASSIFICATION:

Trade or Proprietary Name:	Vortek® Single Loop Ureteral Stent
Common or Usual Name:	Ureteral Stent
Classification Name:	Stent, Ureteral
Classification Number:	876.4620
Regulatory Class:	II
Product Code:	FAD (stent, ureteral)
Advisory Panel:	Gastroenterology/Urology

III. PREDICATE DEVICE

Primary predicate: Hydrogel Coated Percuflex® Drainage Catheters (K924608)
Secondary predicate: Vortek® Double Loop Ureteral Stents (K180057)

These predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Vortek Single Loop Ureteral Stents are self-retaining catheters used to maintain drainage of the upper urinary tract following an intervention on the ureter/bladder or in the case of an obstacle such as calculi or stenosis. The devices collect urine from the kidney for short-term (<30 day) drainage and can be connected to a urine bag for collection. It is a prescription only device. Vortek® Single Loop Ureteral Stents are supplied as a kit containing:

- A 90 cm, radiopaque Single Loop Ureteral Stent with diameters from 6 to 8 Fr. The stents come either with an open or closed distal end. The eyelets or holes for drainage are along the entire loop and length of the device for some models or only on the loop for other models. There are markings along the length of the stent to facilitate insertion of the stent. The stents are made of Vortek Material.
- A Polytetrafluoroethylene (PTFE) coated radiopaque guidewire (Seldinger) with a fixed core and flexible end.
- A clamp for immobilizing the guidewire inserted in the stent during the procedure.
- Luer connector to connect the Single Loop Stent to the latex connector.
- A latex connector, for connection to a urine bag conical connector.

V. INDICATIONS FOR USE

Surgical indication

The Vortek® Single Loop Ureteral Stent is intended for use in ureterostomy or vesical replacement in adult and pediatric (adolescents, children, and infants) patients requiring endourological procedure and /or short-term (less than 30 days) drainage of the upper urinary tract.

Endoscopic indication

The Vortek® Single Loop Ureteral Stent is intended for short-term (less than 30 days) drainage of urine from the upper urinary tract over fistulas or ureteral obstacles in adult and pediatric (adolescents, children, and infants) patients.

The subject and predicate device have the same intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device & Predicate Device(s):	**K201436**	**K924608**	**K180057**
Materials	Vortek Material	copolymer	Vortek Material
Configuration	 One loop	 One loop	 Two loops
Indwelling duration	Less than 30 days	Up to 90 days	Up to 180 days
Size (Fr)	6 to 8 Fr	6 to 8 Fr	4.8 to 8.0 Fr
Length (cm)	90 cm	80 cm	12- 30 cm
Eyes	Eyelets on straight part and loop or only on the loop	Eyelet on loop and straight part	Eyelets on straight part and loop or only on the loop
Coating	No	Hydrogel	No
Sterile	Yes	Yes	Yes
Shelf Life	5 years	Unknown	5 years
Guidewire	PTFE-coated stainless steel	Unknown	PTFE-coated stainless steel or hydro-coated Nitinol guidewire

As evidenced by the above table, the subject and predicate devices have different technological characteristics. However, the differences in technological characteristics do not raise different questions of safety or effectiveness.

VII. SUMMARY OF TESTING PERFORMED

The sponsor provided the following performance testing to support substantial equivalence:

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2009): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff – June 16, 2016. The biocompatibility of the Vortek Single Loop Ureteral Stent included:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material-mediated pyrogenicity
- Subchronic toxicity
- Genotoxicity
- Implantation
- Chemical characterization
- Toxicological Risk evaluation

Mechanical Testing

The following mechanical testing was completed using the FDA guidance document "Guidance for the content of premarket notifications for ureteral stents" February 1993.

- Flow Rate
- Elongation/Yield and tensile strength
- Curl (Loop) Strength
- Shelf Life/Expiration date
- Visual and dimensional testing
- Guidewire compatibility
- Radiopacity
- Magnetic resonance compatibility

Sterilization

The Vortek Single Loop Ureteral Stents and accessories are sterilized using ethylene oxide in a validated cycle demonstrating a sterility assurance level (SAL) of 10^{-6}.

Shelf Life

The Vortek Single Loop Ureteral Stent was subjected to package integrity testing and performance verification testing to support the proposed shelf life.

The protocol and results of the provided performance testing to support substantial equivalence are acceptable.

VIII. CONCLUSION

The subject device is substantially equivalent to the predicate device.