February 16, 2022

Coloplast Corp
Gayatri Ghadge
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K213186
Trade/Device Name: NovoFlow™ Reinforced Ureteral Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: January 19, 2022
Received: January 20, 2022

Dear Gayatri Ghadge:

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/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) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213186

Device Name
NovoFlow™ Reinforced Ureteral Stent

Indications for Use *(Describe)*

The NovoFlow Reinforced ureteral stents are intended for patients 12 years of age (40 kg) and over for drainage of the upper urinary tract over fistulas or ureteral obstacles and/or for healing of the ureter. These stents may remain implanted for up to 6 months.

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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5. 510(k) SUMMARY

I. SUBMITTER INFORMATION

510(K) Owner's Name: Coloplast A/S

Legal Manufacturer Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Phone: 612-422-3206
Email: usggh@coloplast.com

Name of Contact Person: Gayatri Ghadge
Principal Regulatory Affairs Specialist

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: January 19, 2022

II. DEVICE

Trade or Proprietary Name: NovoFlow™ Reinforced Ureteral Stent

Common or Usual Name: Ureteral Stents

Classification Name: Stent, Ureteral
(21 CFR section 876.4620)
Product Code: FAD
Device Class: II

III. PREDICATE DEVICE IDENTIFICATION

Predicate device: Vortek® Double Loop Ureteral Stents (K180057).

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

NovoFlow Reinforced Ureteral Stents are implantable ureteral stents used to maintain urine drainage and allow healing of the ureter. They are inserted into the ureter during a surgical procedure using mainly a retrograde technique, although an antegrade approach is also possible.

The stents are supplied in 7 Fr or 8 Fr diameters and lengths from 26 cm through 30 cm, with both tips open (O/O). NovoFlow Reinforced Ureteral Stents are supplied in kits which contain the following components:

- A double loop ureteral stent

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- A steerable pusher, packed separately

Also contained in some kits:

- An Orchestra® Hydrophilic guidewire, packed separately

The NovoFlow Reinforced Ureteral Stents and accessories included in the kits are supplied sterile via ethylene oxide. The ureteral stent and each accessory are packaged and sterilized separately prior to being combined in the kit.

V. INDICATIONS FOR USE

The NovoFlow Reinforced ureteral stents are intended for patients 12 years of age (40 kg) and over for drainage of the upper urinary tract over fistulas or ureteral obstacles and/or for healing of the ureter. These stents may remain implanted for up to 6 months.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

NovoFlow Reinforced Ureteral Stents are substantially equivalent in performance, design and materials to the Vortek® Double Loop Ureteral Stents, cleared under premarket notification number K180057. All devices are tubes made from the same radiopaque, polymeric materials with loops at both the renal and vesical ends to hold the stent in place. Both devices use guidewires and pushers and are intended to be implanted for up to six months. All the devices are sold as kits with the same accessories intended to facilitate implantation. The main differences between the NovoFlow Reinforced Ureteral Stents and the predicate device are that the subject device is available in only 7 and 8 Fr sizes while the predicate device is available in 4.8 – 8 Fr. In addition, some models of the predicate device contain a suture, while the NovoFlow Reinforced Ureteral Stents do not contain a suture.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): 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.

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Mechanical Testing

Mechanical testing was completed using the FDA guidance document "Guidance for the content of premarket notifications for ureteral stents" for reference. The following tests were performed:

- Visual Inspection
- Dimensional Testing
  - Diameter
  - Length
- Flow Rate
- Elongation/Yield and Tensile Strength
- Loop/Curl strength
- Guidewire compatibility
- Radiopacity
- Magnetic resonance compatibility
- Shelf Life/Expiration Date

Sterilization

The NovoFlow Reinforced Ureteral Stents and accessories are sterilized using ethylene oxide in a validated cycle, demonstrating a sterility assurance level of 10^{-6}.

Packaging and Distribution

The NovoFlow Reinforced Ureteral Stents were subjected to distribution testing and verification testing to demonstrate that the product and package would be undamaged throughout the product life and maintain the device sterility.

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The NovoFlow Reinforced Ureteral Stents and related accessories have been demonstrated to be substantially equivalent to the predicate device, Vortek Double Loop Ureteral Stents based on the non-clinical data provided, similar intended use, patient population, implant duration, materials, biocompatibility, kit composition, and technological characteristics. The differences in technological characteristics do not raise new questions of safety or effectiveness.