November 6, 2018

Coloplast Corp
Cori Ragan
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K180469
Trade/Device Name: Silicone Hydro-Coated Double Loop Ureteral Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: October 12, 2018
Received: October 15, 2018

Dear Cori Ragan:

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 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Timothy Martin -S
2018.11.06 15:50:42 -05'00'

for
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)*

K180469

Device Name

Silicone Hydro-Coated Double Loop Ureteral Stent

Indications for Use *(Describe)*

The Silicone Hydro-Coated Double Loop Ureteral Stents are used for:

- drainage of the upper urinary tract over fistulas or ureteral obstacles
- healing of the ureter

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

I. SUBMITTER

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

Legal Manufacturer Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Phone: (612) 597-5106
Email: usclr@coloplast.com

Name of Contact Person: Cori L. Ragan
Regulatory Affairs Manager

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

Date Prepared: 20 February 2018

II. DEVICE

Trade or Proprietary Name: Silicone Hydro-Coated Double Loop Ureteral Stent

Common or Usual Name: Double Loop Ureteral Stents

Classification Name: Stent, Ureteral
(21CFR section 876.4620)
Product Code: FAD
Device Class: 2

III. PREDICATE DEVICE

Silicone Hydro-Coated Double Loop Ureteral Stents are substantially equivalent in performance, indication, design and materials to the primary predicate device, Porges™ Silicone Double Loop Ureteral Stents, cleared under premarket notification number K013921.

In addition to the primary predicate, the Vortek® Hydro-coated Double Loop Ureteral Stent, cleared under premarket notification number K170362, is a secondary predicate for this submission. The Vortek Hydro-coated Double Loop Ureteral Stent has the same intended use but is made from different materials. Both devices include a hydrophilic coating to facilitate insertion of the devices into the patient. The coating minimizes friction and increases comfort for the patient.

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Silicone Hydro-Coated Double Loop Ureteral Stents, along with the predicate devices, Porges™ Silicone Double Loop Ureteral Stents, and Vortek® Hydro-coated Double Loop Ureteral Stent, are implantable autostatic catheters used to maintain urine drainage and to allow for ureteral healing. They are inserted during a surgical procedure using either an antegrade or a retrograde technique or by open surgery typically using a guidewire and a pusher.

Stents are supplied in diameters between 6 and 8 Fr and lengths between 16 and 30 cm long. The stents have both tips open (o/o) to allow for placement over a guidewire.

Silicone Hydro-Coated Double Loop Ureteral Stents in this submission and the predicates are supplied in kits. The ImaJin™ Silicone Hydro-Coated Double Loop Ureteral Stent Kits contain the following components:

- A Silicone Hydro-Coated Double Loop Ureteral Stent
- A steerable pusher

And in some kits:

- A guide wire
- A ureteric catheter

The Silicone Hydro-Coated Double Loop 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 Silicone Hydro-Coated Double Loop Ureteral Stents, and the predicate devices have the same intended use which is:

- Drainage of the upper urinary tract over fistulas or ureteral obstacles
- Healing of the ureter

Both the subject and primary predicate device are intended to be used in both adult and pediatric populations and remain in place for up to twelve months. The secondary predicate device is also used in both adult and pediatric populations and remain in place for up to six months.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Silicone Hydro-Coated Double Loop Ureteral Stents are substantially equivalent in performance, design and materials to the Porges™ Silicone Double Loop Ureteral Stents, cleared under premarket notification number K013921, and Vortek® Hydro-coated Double Loop Ureteral Stent, cleared under premarket notification number K170362. The implantable ureteral stents are tubes made from radiopaque, polymeric materials with loops at both the renal and vesical ends to hold the stent in place. Both devices use guidewires and pushers or direct surgical placement to be implanted for up to twelve months for the primary predicate and up to six months for the secondary predicate device. All the devices are sold as kits with similar accessories intended to

facilitate implantation. The only difference between the subject Silicone Hydro-Coated Double Loop Ureteral Stents and the primary predicate, Porges™ Silicone Double Loop Ureteral Stents is that the subject device includes a lubricious coating to decrease friction during the implant procedure. The secondary predicate also includes a lubricious coating.

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 (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. A comprehensive regimen of testing for the Silicone Hydro-Coated Double Loop Ureteral Stents included:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material-mediated pyrogenicity
- Sub-chronic toxicity
- Genotoxicity
- Implantation – short and long-term
- Chronic Systemic Toxicity
- Extractable and Leachable evaluation
- Toxicological Risk evaluation

Accessories also underwent biocompatibility testing appropriate to their patient contact duration and intended use.

Mechanical Testing

Mechanical testing was completed using the FDA guidance document "Guidance for the content of premarket notifications for ureteral stents" for reference. Testing included:

- Flow Rate
- Elongation / Yield and tensile strength
- Loop Strength
- Shelf life evaluation
- Visual and dimensional testing
- Radiopacity testing
- Magnetic resonance compatibility testing

Sterilization

The Silicone Hydro-Coated Double Loop Ureteral Stents and accessories are sterilized using ethylene oxide in a validated cycle demonstrating a microbial assurance level of 10^{-6}.

Packaging and Distribution

The Silicone Hydro-Coated Double Loop 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 Silicone Hydro-Coated Double Loop Ureteral Stents have demonstrated substantial equivalence to the two predicates, Porges™ Silicone Double Loop Ureteral Stents and Vortek® Hydro-Coated Double Loop Ureteral Stent based on the non-clinical data provided, the same intended use, patient population, implant duration, materials, biocompatibility, kit composition, and technological characteristics.