June 8, 2022

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

Re: K213185
Trade/Device Name: ImaJin® Silicone double loop ureteral stent kits, ImaJin® Pyelostent® Silicone double loop ureteral stent kits, ImaJin® Stenostent® Silicone double loop ureteral stent kits
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: May 6, 2022
Received: May 9, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213185

Device Name
ImaJin® Silicone double loop ureteral stent kits
ImaJin® Pyelostent® Silicone double loop ureteral stent kits,
ImaJin® Stenostent® Silicone double loop ureteral stent kits

Indications for Use *(Describe)*

Silicone double loop ureteral stents:
The Silicone double loop ureteral stents are intended for adult and pediatric (children and adolescents) patients 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 12 months.

Pyelostent and Stenostent Silicone double loop ureteral stents:
Drainage of the upper urinary tract and/or ureter healing during management of ureteral stenosis:

For Pyelostent® Silicone double loop ureteral stents:
Partial enlargement of the stent diameter, for localized stenosis of the ureteropelvic junction in adult and pediatric (adolescents) patients.

For Stenostent® Silicone double loop ureteral stents:
Total enlargement of the stent diameter, for ureteral stenosis in adult and pediatric (children and adolescents) patients.

The Pyelostent® and Stenostent® Silicone double loop ureteral stents may remain implanted for up to 12 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.

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"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."

5. 510(k) SUMMARY

I. SUBMITTER

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

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 North
Minneapolis, MN 55411

Date Prepared: June 7, 2022

II. DEVICE

Device Name: Imajin® Silicone double loop ureteral stent kits
ImaJin® Pyelostent® Silicone double loop ureteral stent kits
ImaJin® Stenostent® Silicone double loop ureteral stent kits

Common or Usual Name: Double Loop Ureteral Stents

Classification Name: Stent, Ureteral
Classification Number: 21 CFR section 876.4620
Product Code: FAD
Regulatory Class: 2

III. PREDICATE AND REFERENCE DEVICES

Predicate Device: Porges™ Silicone Double Loop Ureteral Stents, K013921
Reference Device: Silicone Hydro-coated double loop ureteral stent, K180469

The predicate and reference devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The ImaJin Silicone double loop ureteral stent kit product family was originally cleared as Porges™ Silicone Double Loop Ureteral Stents in 510(k) K013921. The ImaJin Silicone double loop ureteral stent family consists of three single use, autostatic stents intended to drain the upper urinary tract and allow healing in case of ureteral obstacles or damage to the ureter. The Pyelostent and Stenostent Silicone double loop ureteral stents have partial and complete reinforcement along the straight catheter section respectively to add crush resistance. The devices are provided with a

pusher and in some cases a guidewire. The Silicone double loop ureteral stents are ethylene oxide sterilized, single use, implantable devices.

The current submission is to update the indication for use statement, revise the Instructions for Use, add information on MRI compatibility, modify drainage hole size in some models, modify packaging, and modify the device performance specifications.

V. INDICATIONS FOR USE

Silicone double loop ureteral stents:
The Silicone double loop ureteral stents are intended for adult and pediatric (children and adolescents) patients 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 12 months.

Pyelostent and Stenostent Silicone double loop ureteral stents:
Drainage of the upper urinary tract and/or ureter healing during management of ureteral stenosis:

For Pyelostent® Silicone double loop ureteral stents:
Partial enlargement of the stent diameter, for localized stenosis of the ureteropelvic junction in adult and pediatric (adolescents) patients.

For Stenostent® Silicone double loop ureteral stents:
Total enlargement of the stent diameter, for ureteral stenosis in adult and pediatric (children and adolescents) patients.

The Pyelostent® and Stenostent® Silicone double loop ureteral stents may remain implanted for up to 12 months.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Imajin® Silicone double loop ureteral stent kits, ImaJin® Pyelostent® silicone double loop ureteral stent kits, and ImaJin® Stenostent® silicone double loop ureteral stent kits are currently cleared for the US market under the predicate 510(k) Porges™ Silicone Double Loop Ureteral Stents, K013921. The proposed changes to the previously cleared devices do not alter the performance or intended use of the products. The ImaJin Silicone double loop ureteral stent family has equivalent design, function, packaging, sterilization process, materials, fundamental technology, indications for use and operating principles as the predicate device. The differences in indications for use, contraindications, MRI compatibility, packaging, and performance specifications do not significantly alter the device compared to the primary predicate. The modified performance specifications are the same as for the reference device, Silicone Hydro-coated double loop ureteral stent, K180469.

VII. PERFORMANCE DATA

The following performance data was provided for the proposed changes and to support the substantial equivalence determination.

Mechanical/Performance Testing

- Visual Evaluation
- Dimensional Testing
    - Shaft Diameter and Length
- Guidewire and Pusher Compatibility
- Liquid Compatibility
- Flowrate per EN 1618:1997
- Glide on Guidewire (Friction)
- Tensile Strength Testing per EN 1618:1997
- Elongation
- Loop Strength
- Radiopacity
- Shelf Life/Expiration date
- MRI Safety Testing
- Package Integrity Testing
- Transportation Testing

Sterilization

The Imajin Silicone double loop ureteral stent kits, ImaJin Pyelostent Silicone double loop ureteral stent kits, and ImaJin Stenostent Silicone double loop ureteral stent kits are sterilized using ethylene oxide in a validated cycle in conformance with ISO 11135-2014, demonstrating a sterility assurance level (SAL) of 10^{-6}.

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

VIII. CONCLUSIONS

Based upon the intended use, technological characteristics, and non-clinical performance data provided, the Imajin Silicone double loop ureteral stent kits, ImaJin Pyelostent Silicone double loop ureteral stent kits, and ImaJin Stenostent Silicone double loop ureteral stent kits have been demonstrated to be substantially equivalent to the predicate, Porges™ Silicone Double Loop Ureteral Stents, cleared under premarket notification number K013921. The changes do not raise new questions of safety or effectiveness and the subject devices are as safe and effective as the predicate device.