June 11, 2020

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

Re: K201007
Trade/Device Name: In-Ka® Ureteral Balloon Dilatation Catheters
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: April 15, 2020
Received: April 17, 2020

Dear Cori L. 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/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,

Purva Pandya
Acting 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)*

K201007

Device Name

In-Ka® Ureteral Balloon Dilatation Catheters

Indications for Use *(Describe)*

In-Ka® ureteral balloon dilatation catheters are intended for:

- Dilation of ureteral meatus and/or ureteral canal during endoscopic procedures
- Treatment of ureteral stenosis

Target population

Patients requiring endourologic procedures and/or presenting with ureteral stenosis.

Duration of Use

In-Ka® ureteral balloon dilatation catheters are intended for transient use (less than 1 hour).

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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5. 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 North
Minneapolis, MN 55411

Date Prepared: 15-Apr-2020

II. DEVICE

Trade or Proprietary Name: In-Ka® Ureteral Balloon Dilatation Catheter

Common or Usual Name: Ureteral Balloon Dilatation Catheter

Classification Name: Dilator, Catheter, Ureteral
(21 CFR section 876.5470)
Product Code: EZN
Device Class: 2

III. PREDICATE DEVICE

The In-Ka Ureteral Balloon Dilatation Catheters are substantially equivalent in performance, indication, design and materials to Bard® Uroforce™ Balloon Dilation Catheters, cleared under premarket notification number K993840.

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

IV. DEVICE DESCRIPTION

The In-Ka Ureteral Balloon Dilatation Catheter is a urinary balloon catheter intended for dilation of the ureteral meatus or the ureteral canal or for treatment of ureteral stenosis. The catheter is a double lumen catheter with a balloon at the distal end and supplied in three balloon diameters ranging from 4 – 6 mm. Each 75 cm long In-Ka catheter is supplied sterile for a single use. Either a manometer or a 10cc syringe is included for balloon inflation.

V. INDICATIONS FOR USE

In-Ka ureteral balloon dilatation catheters are intended for:
• Dilation of ureteral meatus and/or ureteral canal during endoscopic procedures
• Treatment of ureteral stenosis

Target population
Patients requiring endourologic procedures and/or presenting with ureteral stenosis.

Duration of Use
In-Ka ureteral balloon dilatation catheters are intended for transient use (less than 1 hour).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The In-Ka Ureteral Balloon Dilatation Catheters are substantially equivalent in performance, indication, design and materials to Bard Uroforce Balloon Dilation Catheters, cleared under premarket notification number K993840. There are no significant technological differences between the subject devices and the predicate. Bard Uroforce Balloon Dilation Catheters (predicate) and the In-Ka Ureteral Balloon Dilatation Catheter (subject device) are each supplied with inflation devices which can either be a manometer or a syringe. Both the subject and predicate devices have dual lumens to allow for similar size guidewires (0.035 inch for In-Ka and 0.038 inch for Uroforce) and for balloon inflation. The recommended balloon inflation pressures are a maximum of 17 atm for the In-Ka balloon and 23 atm for the Uroforce balloon. The In-Ka balloon diameters and lengths (4 – 6 mm diameter and 40 mm long) fall within the range covered in the Bard Uroforce Balloon Dilation Catheter (4-8 mm diameter and 4 – 10 cm long). Both devices are 75 cm long, supplied sterile, and intended for a single use.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the In-Ka Ureteral Balloon Dilatation Catheters device was conducted in accordance with ISO 10993-1 and FDA guidance document for Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process". The In-Ka Ureteral Balloon Dilatation Catheters are categorized as surface devices (natural route) or as externally communicating devices (percutaneous route) coming in contact with mucous membrane (natural route) or tissues (suprapubic route) for limited (<24h) duration of time.

The battery of biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

- Acute Systemic toxicity

Performance Testing

Performance testing was conducted with samples before and after accelerated aging. The battery of performance testing included the following tests:

- Visual evaluation
- Balloon testing
  - Balloon diameter
  - Balloon deflated profile
  - Balloon Inflation / Deflation Time
  - Balloon compliance
  - Balloon sheath removal force
  - Balloon Cycle Testing / Multiple inflation testing
  - Balloon Burst Testing
- Dimensional Testing
  - Catheter tip length
  - Shaft diameter and length
  - Radiopaque marker band to balloon alignment
- Catheter Preparation, deployment, and retraction (simulated use)
- Injection Luer Compatibility
- Radiopacity
- Tensile strength testing
  - Catheter shaft
  - Catheter / Connector junction
  - Luer connector bond
  - Marker band removal force
- Guidewire compatibility
- High Pressure Test
  - Nominal burst pressure
  - Maximum burst pressure
  - Burst mode (radial vs. longitudinal)
- Manometer performance verification

The results of the performance testing demonstrate equivalence of the In-Ka Ureteral Balloon Dilatation Catheters to the predicate device. The In-Ka Ureteral Balloon Dilatation Catheters are considered safe and effective for their intended use.

Sterilization

The In-Ka Ureteral Balloon Dilatation Catheter and accessories are sterilized using ethylene oxide in a validated cycle demonstrating a microbial assurance level of 10^{-6}.

Packaging and Distribution

The In-Ka Ureteral Balloon Dilatation Catheter and accessories 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 was provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The In-Ka Ureteral Balloon Dilatation Catheter and related accessories are substantially equivalent to the Bard Uroforce Balloon Dilation Catheters based on the non-clinical data provided, the same intended use, patient population, biocompatibility, kit composition, and technological characteristics.