December 17, 2020

Coloplast Corp.
Sihem Darraji
Corporate Director, Global Regulatory Affairs
1601 West River Road North
Minneapolis, MN 55411

Re: K201165
Trade/Device Name: In-Ka® Percutaneous Balloon Dilatation Catheter and Amplatz Sheath
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LJE
Dated: November 13, 2020
Received: November 16, 2020

Dear Sihem Darraji:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201165

Device Name

In-Ka® Percutaneous Balloon Dilatation Catheter and Amplatz Sheath

Indications for Use *(Describe)*

The In-Ka® Percutaneous Balloon Dilatation Catheters are indicated for dilation of the tract to create a percutaneous renal access in patients requiring a percutaneous renal procedure for urine drainage or therapeutic action. The balloon catheter is designed for transient use (for the duration of the percutaneous tract dilation).

The Amplatz sheath is used during renal dilation to provide and maintain a nephrostomy tract in patients requiring a percutaneous renal procedure for urine drainage or therapeutic action. It is designed for short-term use (up to 3 hours).

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.

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510(k) SUMMARY – K201165

I. SUBMITTER

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

Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Office: 612.597.5106
Email: usclr@coloplast.com

Name of Contact Person: Sihem Darraji
Corporate Director, Global Regulatory Affairs

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

Date Prepared: December 17, 2020

II. DEVICE

Trade or Proprietary Name: In-Ka® Percutaneous Balloon Dilatation Catheter and Amplatz Sheath

Common or Usual Name: Nephrostomy Catheter

Classification Name: Catheter, Nephrostomy
Product Code: LJE
Device Class: Unclassified

III. PREDICATE DEVICE

Bard X-Force™ N30 Nephrostomy Balloon Dilation Catheters, cleared under premarket notification number K080944

The predicate device has the following indication for use:

- Dilation of the nephrostomy tract and placement of the working sheath

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® Percutaneous Balloon Dilatation Catheters are balloon catheters intended for dilation of the nephrostomy tract to create a percutaneous renal access.

The catheter is a 7 Fr double lumen catheter supplied with a radiopaque Amplatz sheath. The catheter is supplied with or without an inflation device (manometer) depending on the model. Amplatz sheaths are also sold separately from the catheter.

The 30 Fr balloon is equipped with a radiopaque stainless-steel ring on its distal extremity corresponding to the balloon's working length to allow radiographic visualization and positioning. Each In-Ka catheter is supplied sterile for a single use.

V. INDICATIONS FOR USE

The In-Ka® Percutaneous Balloon Dilatation Catheters are indicated for dilation of the tract to create a percutaneous renal access in patients requiring a percutaneous renal procedure for urine drainage or therapeutic action. The balloon catheter is designed for transient use (for the duration of the percutaneous tract dilation).

The Amplatz sheath is used during renal dilation to provide and maintain a nephrostomy tract in patients requiring a percutaneous renal procedure for urine drainage or therapeutic action. It is designed for short-term use (up to 3 hours).

The subject and predicate device have the same intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate device have different technological characteristics, including lumen length and material, balloon length and material, and balloon max pressure. These differences in technological characteristics do not raise different questions of safety and effectiveness.

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. The following biocompatibility testing was completed:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity

The protocol and results of biocompatibility testing were acceptable.

Mechanical Testing

Performance testing was conducted with samples aged at T=0 and 3 years accelerated aging. The performance testing included the following tests:

<u>In-Ka Percutaneous Balloon Dilatation Catheter Testing</u>

- Visual evaluation
- Dimensional Testing
    - Balloon deflated profile
    - Catheter tip length
    - Balloon diameter
    - Balloon length
    - Radiopaque marker band to balloon alignment
    - Shaft diameter and length
- Balloon testing
    - Balloon sheath removal force
    - Simulated Use Catheter Preparation, deployment, and retraction
    - Balloon Inflation / Deflation Time
    - Balloon compliance
    - Balloon Cycle Testing / Multiple inflation testing
    - Balloon Burst
- Marker Band Removal Force
- Radiopacity
- Guidewire compatibility with distal Channel
- Compatibility with Amplatz Sheath
- High Pressure Test
    - Nominal burst pressure

  - Maximum burst pressure
- Injection Luer Compatibility
- Tensile strength testing
  - Catheter shaft
  - Catheter / Connector junction
  - Luer connector

Amplatz Sheath

- Visual Evaluation
- Radiopacity
- Compression Resistance
- Dimensional Evaluations
  - Length
  - Inner Diameter
  - External Diameter
  - Bevel Angle

Manometer

- Pressure Accuracy Testing

The results of mechanical performance tests were acceptable.

Sterilization

The In-Ka Percutaneous Balloon Dilatation Catheters and Amplatz Sheaths are sterilized using ethylene oxide in a validated cycle demonstrating a sterility assurance level (SAL) of 10^{-6}.

Shelf Life

The In-Ka Percutaneous Balloon Dilatation Catheter was subjected to package integrity testing and verification testing to support the proposed shelf life.

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

VIII. CONCLUSIONS

The In-Ka Percutaneous Balloon Dilatation Catheter and the Amplatz Sheath have been demonstrated to be substantially equivalent to the predicate, Bard X-Force N30 Nephrostomy Balloon Dilation Catheters.