DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 17, 2017

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

Re: K170531
Trade/Device Name: Ureteral Dilators and Percutaneous Nephrostomy Dilators
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: August 10, 2017
Received: August 14, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170531

Device Name
Ureteral Dilators and Percutaneous Nephrostomy Dilators

Indications for Use *(Describe)*

Ureteral Dilators:
Intended to be used for dilatation of the ureter during ureteroscopic procedures.

Percutaneous Nephrostomy Dilators:
Dilator for tract preparation or splittable working sheath to protect the parenchyma.

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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7. 510(k) SUMMARY

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:	Cori Ragan Regulatory Affairs Manager
Address/Contact:	1601 West River Road Minneapolis, MN 55411
Date Prepared:	21 February 2017
Trade or Proprietary Name:	Ureteral Dilator Percutaneous Nephrostomy Dilators
Common or Usual Name:	Ureteral Dilator Percutaneous Nephrostomy Dilators
Classification Name:	Ureteral dilator (21CFR section 876.5470) (Product Code: EZN) Device Class: 2

Legally Marketed Device to Which Your Firm is Claiming Equivalence:

The Ureteral and Percutaneous Nephrostomy Dilators are substantially equivalent in performance, indication, design and materials to Cook Medical AQ® Hydrophilic Dilator, cleared under premarket notification number K961904.

Device Description:

Ureteral dilators:

The Ureteral Dilators are hollow rigid tubes made of Polyether Block Amide (PEBA) with tapered tips at the distal and proximal end. Total length is approximately 48 cm.

The dilators are compatible with a 0.038 inch (0.97 mm) guidewire. Outer diameters are either:

- CH FR 08 at one end and CH FR 10 at the other end
- CH FR 12 at one end and CH FR 14 at the other end

Percutaneous Nephrostomy (PCN) dilators:

The simple dilators are hollow tubes made in Polyether Block Amide (PEBA), with a tapered distal tip and straight cut proximal end. Total length is approximately 21cm.

The dilators are compatible with a 0.038 inch (0.97mm) guide-wire.

The dilator with splittable sheath consists of a high-density polyethylene (HDPE) dilator fitted with a Polytetrafluoroethylene (PTFE) sheath.

Intended Use of the device:

Ureteral dilators:
Intended to be used for dilatation of the ureter during ureteroscopic procedures.

Percutaneous Nephrostomy Dilators:
Dilator for tract preparation or splittable working sheath to protect the parenchyma.

Technological Characteristics Compared to Predicate Device:

The Ureteral and Percutaneous Nephrostomy Dilators are substantially equivalent in performance, design and materials to Cook Medical AQ® Hydrophilic Dilator, cleared under premarket notification number K961904.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence is supported by bench testing comparing Ureteral and Percutaneous Nephrostomy Dilators to the predicate device and biocompatibility testing performed on the Ureteral and Percutaneous Nephrostomy Dilators.