November 2, 2017

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

Re: K170422
Trade/Device Name: Biosoft® duo Double Loop Ureteral Stents
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: September 20, 2017
Received: September 21, 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.

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.

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,

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)*
K170422

Device Name
Biosoft® duo Double Loop Ureteral Stents

Indications for Use *(Describe)*
The 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

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 September 2017
Trade or Proprietary Name:	Biosoft® duo Double Loop Ureteral Stent
Common or Usual Name:	Biosoft® duo Double Loop Ureteral Stent
Classification Name:	Stent, Ureteral (21CFR section 876.4620) Product Code: FAD Device Class: 2

Legally Marketed Device to Which Your Firm Is Claiming Equivalence:

Biosoft duo Double Loop Ureteral Stents and their accessories are substantially equivalent in performance, indication, design and materials to Biosoft Ureteral Double Loop Stents from Coloplast A/S, cleared under premarket notification numbers K881744 and K981591.

Device Description:

The Biosoft duo Double loop ureteral stents are flexible tubular devices designed with open renal and open vesical ends to be inserted with a guidewire using a pusher. The stents are radiopaque for fluoroscopic visualization. They have eyes on the straight part. Stent diameters and length vary to accommodate the patient's anatomy. A withdrawal thread is attached on the proximal end to allow removal.
Non-steerable pushers are simple tubes, the clamp can be used to immobilize the pusher onto the guidewire. Steerable pushers are equipped with a blue handle/Luer Lock female connector and made of an inner tube that can move forward and backward inside an external tube, to allow connection/disconnection of the stent.
The ureteric catheter supplied with a connector fitted with a Luer tip can be used for inserting the guidewire or injecting contrast medium.

The Biosoft duo Double Loop Ureteral Stents in this submission and the predicate Biosoft Double Loop ureteral stents are supplied in kits which are comprised of any of the following components depending of the reference of the kit:

- A double-loop ureteral stent equipped with a withdrawal thread
- A non-steerable pusher provided with a clamp, or a steerable pusher
- Available in certain kits:
    - A radiopaque 0.035-inch (0.89mm) diameter guidewire: PTFE-coated stainless steel guidewire or fully hydrophilic nitinol guidewire
    - A ureteric (also called ureteral) catheter

Intended Use of the device:

The Biosoft duo Double Loop Ureteral Stents in this submission and the predicate Biosoft Double Loop ureteral stents have the same intended use:

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

Technological Characteristics Compared to Predicate Device:

The Biosoft duo Double Loop Ureteral stents and their accessories are substantially equivalent in performance, indication, design and materials to Biosoft Ureteral Double Loop Stents from Coloplast A/S, cleared under premarket notification number K981591.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence is supported by bench testing and biocompatibility testing comparing Biosoft duo Double Loop Ureteral stents to the predicate device.