February 12, 2018

Coloplast A/S
Nikita Basandra
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K173527
Trade/Device Name: Digitex Delivery Device
Regulation Number: 21 CFR§ 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Regulatory Class: II
Product Code: PWI
Dated: November 13, 2017
Received: November 14, 2017

Dear Nikita Basandra:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173527

Device Name
Digitex Delivery Device

Indications for Use *(Describe)*
The Digitex Delivery Device is a single-use device intended for use as an aid in suturing during transvaginal pelvic organ prolapse procedures with surgical mesh.

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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Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

510(k) SUMMARY – K173527

510(K) Owner's Name:	Coloplast A/S
Legal Manufacturer Address:	Holtedam 1 3050 Humlebaek, Denmark
Contact Person:	Nikita Basandra Principal Regulatory Affairs Specialist Phone: (612) 505-8779 Email: usnbas@coloplast.com
Address/Contact:	1601 West River Road Minneapolis, MN 55411
Date Prepared:	February 12, 2018
Trade or Proprietary Name:	Digitex® Delivery Device
Common or Usual Name:	Instrumentation for use with urogynecologic surgical mesh
Classification Name: urogynecologic	Specialized surgical instrumentation for use with surgical mesh
Classification Number:	21 CFR 884.4910
Product Code:	PWI (instrumentation, surgical mesh, urogynecologic, transvaginal repair of pelvic organ prolapse)
Device Class:	II
Classification Panel:	Obstetrics and Gynecology
Predicate Device:	The Digitex® Delivery Device is substantially equivalent in performance, indication, design and materials to the Capio SLIM Suture Capturing Device, cleared under K172060 on November 3, 2017. The predicate device has not been subject to a design-related recall.

Device Description:

The Digitex® Suture Delivery System is composed of a delivery device and suture cartridge and is designed for use by the physician to facilitate the consistent placement of suture when direct visualization is not possible and/or the anatomical location is difficult to reach. The shaft of the device has been designed to allow for adjusting the angle of the needle housing to further facilitate suture placement in the desired location.

Intended Use of the device:

The Digitex Delivery Device is a single-use device intended for use as an aid in suturing during transvaginal pelvic organ prolapse procedures with surgical mesh.

Predicate Device Comparison:

The subject and predicate device have the same intended use – aid in the placement of urogynecologic surgical mesh.

The subject and predicate device have different technological characteristics including material composition and dimensions. These differences in technological characteristics do not raise different questions of safety and effectiveness.

Nonclinical Performance Testing:

The following non-clinical performance tests were performed on the subject device, per the special controls listed in 21 CFR 884.4910:

- Biocompatibility testing per ISO 10993-1 and FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process."
    - Cytotoxicity
    - Sensitization
    - Irritation
- Sterilization validation
- Package integrity testing
    - Simulated shipping and handling
    - Bubble leak testing
    - Seal strength testing
- Dimensional analysis
- Mechanical performance testing evaluating key potential failure modes
- Shelf life Testing

The results of all performance testing met pre-defined acceptance criteria as applicable and are acceptable.

Conclusion

The results of the performance testing described above demonstrate that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.