September 25, 2023

Coloplast A/S
Jennifer Mrkvicka
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K231891
Trade/Device Name: Virtue Male Sling System with Alexis Wound Retractor Convenience Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTM, GAD
Dated: June 27, 2023
Received: June 27, 2023

Dear Jennifer Mrkvicka:

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,

Angel A. Soler-garcia -S

for
Jessica K. Nguyen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231891

Device Name
Virtue® Male Sling System with Alexis® Wound Retractor

Indications for Use *(Describe)*
The Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

The Applied Alexis Wound Retractor is indicated for use to:

Access the abdominal cavity during surgery through an atraumatically retracted incision.
Deliver maximum exposure of the abdominal cavity with minimum incision.
Protect against wound contamination during laparoscopic and open surgery.

The smaller two sizes of Alexis are also intended to be used to:

Seal off the incision opening to permit insufflating the peritoneum.
Convert the incision wound to an additional trocar port site.
Access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures through an atraumatically-retracted incision.

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.

510(k) SUMMARY

I. SUBMITTER

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

Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Email: Office: 612-707-5062
Email: usjmrk@coloplast.com

Name of Contact Person: Jennifer Mrkvicka
Principal Regulatory Affairs Specialist

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

Date Prepared: September 18, 2023

II. DEVICE

Trade or Proprietary Name: Virtue® Male Sling System with Alexis® Wound Retractor

Common or Usual Name: Surgical Mesh

Classification Name: Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Retractor (GAD)

Review Panel: Gastroenterology/Urology

Classification Number: 21 CFR 878.3300 (OTM)
21 CFR 878.4800 (GAD)

Product Code: OTM (Virtue)
GAD (Alexis)

Product Classification: Class II (Virtue)
Class I (Alexis)

III. PREDICATE DEVICE

510(k) Number: K113496

Trade Name: Virtue Male Sling System with Alexis Wound Retractor

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

IV. DEVICE DESCRIPTION

The Virtue Male Sling is an implantable, suburethral support sling intended for the surgical treatment of male stress urinary incontinence (SUI). The four-arm design of the Virtue Male Sling provides a dual mechanism of action by providing both compression of the bulbous urethra and proximal urethral elevation. The Virtue Male Sling is constructed of non-absorbable medical grade knitted, monofilament polypropylene and is intended to be permanently implanted.

The Virtue Introducer is used to facilitate transobturator and pre-pubic passages during the surgical placement of the Virtue Male Sling. The introducer is manufactured from polycarbonate thermoplastic elastomer (handle) and medical grade stainless steel (needle). The Virtue Introducer is only to be used with the Virtue Male Sling System in accordance with the Instructions for Use.

The Virtue Male Sling System with Alexis Wound Retractor includes one (1) Virtue Male Sling, one (1) single-use Virtue Introducer and one (1) Alexis Wound Retractor intended to facilitate the placement of the Virtue Male Sling.

V. INDICATIONS FOR USE

The Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

The Applied Alexis Wound Retractor is indicated for use to:

- Access the abdominal cavity during surgery through an atraumatically retracted incision.
- Deliver maximum exposure of the abdominal cavity with minimum incision.
- Protect against wound contamination during laparoscopic and open surgery.

The smaller two sizes of Alexis are also intended to be used to:

- Seal off the incision opening to permit insufflating the peritoneum
- Convert the incision wound to an additional trocar port site.
- Access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures through an atraumatically-retracted incision.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Virtue Male Sling System has identical indications for use, design, materials, and target population as the predicate device. In this 510(k) submission, Coloplast A/S only provided revised labeling; there are no changes to the device itself. The labeling revisions include, but are not limited to, the addition of a contraindication to align with other Coloplast mesh Instructions for Use (IFU) manuals, updates to adverse events based on post market surveillance and literature analysis, and procedure updates aligned with current literature. The differences in device labeling do not raise questions of safety or effectiveness, and the subject device was found to be substantially equivalent with the predicate.

VII. PERFORMANCE DATA

Performance data was not necessary for the substantial equivalence determination as the subject device and the predicate device have identical intended use, target population, sterilization technique, biocompatibility features, overall device design features, and duration of use.

VIII. LABELING

In this 510(k), Coloplast A/S revised the IFU to add a contraindication to align with other Coloplast mesh IFUs, updated adverse events based on post market surveillance and literature analysis, and aligned the surgical procedure with current literature.

IX. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the Virtue Male Sling System with Alexis Wound Retractor is substantially equivalent to the predicate.