February 15, 2023

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

Re: K221874
Trade/Device Name: Altis® Single Incision Sling
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: PAH
Dated: January 16, 2023
Received: January 17, 2023

Dear Lauren Portinga:

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,

Jessica K. Nguyen -S

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

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)*
K221874

Device Name
Altis® Single Incision Sling

Indications for Use *(Describe)*
The Altis® Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

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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510(k) SUMMARY

I. SUBMITTER

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

Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Office: (763) 607-6657
Email: uslpo@coloplast.com

Name of Contact Person: Lauren Portinga,
Principal Regulatory Affairs Specialist

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

Date Prepared: February 10, 2023

II. DEVICE

Trade or Proprietary Name: Altis® Single Incision Sling

Common or Usual Name: Surgical Mesh
Classification Name: Mesh, Surgical
Classification Number: 21 CFR 878.3300
Product Code: PAH
Regulatory Class: II
Review Panel: Gastroenterology/Urology

III. PREDICATE DEVICE

510(k) Number: K121562
Trade Name: Altis® Single Incision Sling System

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

IV. DEVICE DESCRIPTION

The Coloplast Altis Single Incision Sling (SIS) System includes an implantable, non-absorbable, single incision mid-urethral sling and disposable introducer needles for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD). The Altis sling is knitted to 1.1 cm width using a 0.08mm (nominal) diameter polypropylene filament and is 7.75 cm long. The Altis sling and Altis introducers are provided sterile (ethylene oxide sterilization) and are for single-use only.

V. INDICATIONS FOR USE

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device and the predicate device (K121562) have identical intended use, target population, sterilization technique, biocompatibility features, overall device design features, and duration of use. In this Special 510(k), Coloplast A/S only provided revised labeling, and there are no changes to the device itself. The labeling revisions only include added information about a completed 522 study in the instructions for use manual. This difference in device labeling does not raise different questions of safety or effectiveness, and the subject 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 Special 510(k), Coloplast A/S revised their instructions for use manual to include a summary of the safety and effectiveness information collected from their completed 522 study.

IX. CONCLUSION

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.