June 10, 2022

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

Re: K220420
Trade/Device Name: Saffron™ Fixation System
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: PBQ
Dated: May 9, 2022
Received: May 10, 2022

Dear Gayatri Ghadge:

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,

Jason R. Roberts, 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)*
K220420

Device Name
Saffron™ Fixation System

Indications for Use *(Describe)*

The Saffron™ Fixation System is indicated for attaching suture to ligaments of the pelvic floor.

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

I. SUBMITTER

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

Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Office: 612-422-3206
Email: usggh@coloplast.com

Name of Contact Person: Gayatri Ghadge
Principal Regulatory Affairs Specialist

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

Date Prepared: June 7, 2022

II. DEVICE

Trade or Proprietary Name: Saffron™ Fixation System

Common or Usual Name: Pelvic ligament fixation system
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Product Code: PBQ (Fixation, Non-Absorbable Or Absorbable, For Pelvic Use)
Regulatory Class: II

III. PREDICATE DEVICE

Anchorsure, 510(k)-cleared on October 12, 2012 under K120831.

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Saffron Fixation System consists of a single-use disposable Saffron Fixation Tool (delivery tool) and implantable tissue fixation Saffron Anchors (packaged and sold separately) made of polysulfone that are intended to be compatible with commercially available sutures up to size 0 (not provided as a part of the system). The delivery tool facilitates anchor placement with or without direct visualization and may be used to implant multiple anchors in a single patient as needed by the surgeon. The fixation anchors are multi-barbed hooks that provide permanent fixation points for suture attachment to the sacrospinous ligament..

The physician transvaginally inserts the distal end of the delivery tool with a loaded anchor through the dissected tissue to the desired location. The physician manually positions the tip of the distal end at the location where the anchor is to be placed and manually presses the plunger advancing the cannula in the fixation tool and releasing the anchor into the tissue. The anchor penetrates the chosen landmark to provide a permanent fixation point for the loaded suture.

The Saffron Fixation device is a single use device which is supplied sterile. The Saffron Anchor is an implantable device which is supplied sterile. The Saffron Fixation System has a shelf life of 6 months.

V. INDICATIONS FOR USE

The Saffron™ Fixation System is indicated for attaching suture to ligaments of the pelvic floor.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device	**Predicate Device**
	Saffron Fixation System K220420	**Anchorsure K120831**
Regulation Number	21 CFR 884.4530	21 CFR 884.4530
Product Code	PBQ	PBQ
Indications for Use	The Saffron™ Fixation System is indicated for attaching suture to ligaments of the pelvic floor.	Anchorsure is indicated for attaching suture to ligaments of the pelvic floor.
Target Structures	Pelvic floor ligaments	Pelvic floor ligaments
Anchor Placement Duration	Permanent Implant	Permanent Implant
Anchor Materials	Polysulfone, titanium oxide colorant	Polyether ether ketone (PEEK)
Anchor Dimensions	Length: 9.29 mm Height: 3.44 mm Width: 1.65 mm	Diameter: 3 mm Length: 7 mm
Delivery System Materials	Polypropylene (plunger), polycarbonate (handle), stainless steel 304 (shaft), polycarbonate / acrylonitrile butadiene styrene (ABS) (distal tip)	Stainless steel 303, polyoxymethylene
Delivery System Dimensions	Fixation Tool shaft diameter: 4 mm Fixation Tool shaft length: 200 mm	Anchoring Handle tube diameter: 6 mm Anchoring Handle tube length: 204 mm
Accessories Provided	No, compatible with any suture size 0 or smaller	Yes, USP size 0 polypropylene suture and curved stainless steel

		surgical needle
Sterile	Yes, ethylene oxide	Yes, ethylene oxide

Saffron Fixation System and the Anchorsure are both permanent anchoring devices that can be used to secure the suture to pelvic floor ligaments. Saffron has the same intended use, target population, sterilization technique, and duration of use as the predicate device. The differences between the two devices are the dimensions, provided accessories, anchor and delivery system design, and component materials. These differences do not raise different questions of safety or effectiveness. These differences were evaluated with performance testing to demonstrate substantial equivalence to the predicate device.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2020): *Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process"* and FDA *Guidance for Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff* – September 4, 2020. The delivery tool was evaluated for the following biocompatibility endpoints, in accordance with an external communicating device contacting tissue/bone/dentin for a limited duration (≤ 24 hours):

- Cytotoxicity per ISO 10993-5:2009
- Guinea Pig Maximization Sensitization per ISO 10993-10:2010
- Intracutaneous Reactivity Irritation per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2017
- Material-Mediated Pyrogenicity per USP<151>

The anchor was evaluated for the following biocompatibility endpoints, in accordance with an implant device contacting tissue/bone for a permanent duration:

- Cytotoxicity per ISO 10993-5:2009
- Guinea Pig Maximization Sensitization per ISO 10993-10:2010
- Intracutaneous Reactivity Irritation per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2017
- Material-Mediated Pyrogenicity per USP<151>
- Subacute/subchronic toxicity with intramuscular implantation per ISO 10993-11:2017
- Genotoxicity per ISO 10993-3:2014
- Implantation per ISO 10993-6:2016

Chemical characterization and toxicological risk assessment in accordance with ISO 10993-18:2020 was completed on the anchor to address the biocompatibility endpoints of:

- Chronic toxicity
- Carcinogenicity

Mechanical/ Performance Testing

The below testing was performed:

- Anchor penetration force
- Anchor detachment force
- Cannula compressive strength
- Anchor eyelet strength
- Anchor holding force
- Anchor insertion force
- Anchor tab torque strength
- Anchor tab shear strength
- Anchor tab fracture strength
- Anchor tab removal force
- Anchor eyelet/suture compatibility
- Anchor eyelet capacity
- Anchor MR compatibility assessment per 2014 FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*
- Shaft rotation
- Delivery device maximum actuation force
- Delivery device feedback force
- Delivery device minimum actuation force
- Delivery device shaft stiffness
- Delivery device torque strength
- Delivery device tensile strength
- Delivery device plunger strength
- Visual and dimensional testing of the anchor and delivery device
- Label and barcode evaluation
- Sterile barrier seal strength
- Sterile barrier integrity after aging
- Full package integrity after transportation simulation per ASTM D4169-16
- Shelf Life/Expiration date
- Usability testing per the 2016 FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices*
- Non-clinical Cadaver testing

Sterilization

The Saffron Fixation System is sterilized using ethylene oxide in a validated cycle, demonstrating a sterility assurance level (SAL) of 10^{-6}. Sterilization validation was completed per ISO 11135:2014 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices* and summarized in accordance with the 2016 FDA guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*.

Packaging and Distribution

The Saffron Fixation System was subjected to packaging performance and stability testing to establish compliance with ISO 11607-1:2019 "Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems". Results of testing demonstrate that the sterile barrier packaging systems can withstand the hazards of climatic stressing, transportation, and storage while adequately maintaining the functional integrity of the product and sterile barrier integrity throughout the product's shelf life of 6 months.

Animal/Clinical Testing

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The Saffron™ Tissue Fixation System has been demonstrated to be substantially equivalent to the predicate, Anchorsure, cleared under premarket notification number K120831, based on the non-clinical performance data provided. The Saffron™ Fixation System is as safe and effective as the predicate device to support a substantial equivalence determination.