December 03, 2024

Covidien
Nicole Boroumand
Senior Regulatory Affairs Specialist
60 Middletown Ave
North Haven, Connecticut 06473

Re: K241486
Trade/Device Name: Sofsilk™ Coated Braided Silk Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP
Dated: May 17, 2024
Received: May 24, 2024

Dear Nicole Boroumand:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.12.03 16:07:49 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241486

Device Name
Sofsilk™ Coated Braided Silk Suture

Indications for Use *(Describe)*
Sofsilk™ Coated Braided Silk Sutures are indicated for use in soft tissue approximation and/or ligation.

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- K241486

Date Prepared:	February 14, 2024
Submitter:	Covidien II (subsidiary of Medtronic) 60 Middletown Ave North Haven, CT 06473 United States
Contact:	Nicole Boroumand Senior Regulatory Affairs Specialist 60 Middletown Ave North Haven, CT 06473 United States Telephone: (626) 375-3597 Email: Nicole.boroumand@medtronic.com
Name of Device:	
Trade/Proprietary name:	Sofsilk™ Coated Braided Silk Suture
Common name:	Natural nonabsorbable silk surgical suture
Classification name:	Class II Panel number and product code: GAP Regulation Number 21 CFR 878.5030
Predicate Device:	
Trade/Proprietary name:	Sofsilk™ Coated Braided Silk Suture
Common name:	Silk Suture
Classification name:	Natural nonabsorbable silk surgical suture Panel number and product code: GAP Regulation Number 21 CFR 878.5030
510(k) Number:	K980124
Manufacturer:	UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHC 150 GLOVER AVE NORWALK, CT 06856
Device Description:	Sofsilk™ 6/0 and 7/0 black braided silk sutures are nonabsorbable, sterile, non-mutagenic surgical sutures composed of natural proteinaceous silk fibers called fibroin. This protein is derived from the domesticated silkworm species

Bombyx mori of the family bombycidae. The silk fibers are treated to remove the naturally-occurring sericin gum and braided to produce Sofsilk™ surgical silk sutures. The braided sutures are coated uniformly with silicone to reduce capillarity and to increase surface lubricity, which enhances handling characteristics, ease of passage through tissue, and knot run-down properties. Sofsilk™ sutures are colored black with Logwood extract (21CFR73.1410).

Sofsilk™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures, Sofsilk™ Coated Braided Silk Suture.
Sofsilk™ sutures are indicated for use in soft tissue approximation and/or ligation.

Intended users are healthcare professionals who have been trained in applicable surgical procedures and approaches involving sutures prior to employing this device.

Intended Use: The intended purpose of the device is soft tissue approximation and/or ligation.

Indications for use: Sofsilk™ sutures are indicated for use in soft tissue approximation and/or ligation.

Summary comparing the technological characteristics of the subject and predicate device:

	Subject Device	**Predicate Device** (K980124)	**Comparison**
Intended Use	Sofsilk™ sutures are indicated for use in soft tissue approximation and/or ligation.	Modified Sofsilk™ Suture has indications for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic, microsurgery and neural tissue.	**Similar**, the subject device's intended use is more restrictive than the predicate device. Therefore, there is no concern regarding substantial equivalence.
Classification	Pannel number: 79 Product code: GAP, per 21 CFR 878.5030 Natural nonabsorbable silk surgical suture	Pannel number: 79 Product code: GAP, per 21 CFR 878.5030 Natural nonabsorbable silk surgical suture	**Identical,** therefore no concern regarding substantial equivalence.
Materials	Suture: silk from silkworm dyed with Logwood extract (21CFR73.1410) with a ferrous-based mordant and coated with silicone Needles: Stainless steel with silicone coating	Suture: silk from silkworm Dye: Logwood extract (21CFR73.1410) with a chromium-based mordant Suture coating: MED 2245 Silicone Needles: Stainless steel with silicone coating	**Similar**, the subject device uses a different mordant. The new mordant does not affect performance. Therefore, no concern regarding substantial equivalence.
Sizes	Only sizes 6-0 and 7-0 are in scope for the 510(k).	Sizes 5 through 9-0	**Similar,** the subject device has fewer sizes. Therefore, no concern regarding substantial equivalence.
Product Configurations	pre-cut lengths and ligating reels, non-needled or affixed to needles using both permanent and removable needle attachment techniques.	pre-cut lengths and ligating reels, non-needled or affixed to needles using both permanent and removable needle attachment techniques: in one, two and three dozen box quantities.	**Similar,** the subject device has fewer configurations. Therefore, no concern regarding substantial equivalence.

Sterilization	ETO sterilization with a minimum Sterility Assurance Level (SAL) of 10^{-6}	Gamma radiation (25.1-40 kGy) with a minimum Sterility Assurance Level (SAL) of 10^{-6}	**Different** The subject device is sterilized with ETO sterilization, whereas the predicate device is sterilized via Gamma. The subject's sterilization process results in a SAL of 10^{-6} and is a Category A sterilization method.
Packaging	Tyvek® and nylon pouches or Tyvek® and paper pouches	Tyvek® and nylon/polyethylene pouches or aluminum foil/laminate packages	**Similar,** The subject device can also be packaged in Tyvek® and paper pouch. This additional configuration does not affect sterility or shelf life. Therefore, no concern regarding substantial equivalence.
Shelf life	5 years	5 years	**Identical,** there is no change to shelf life between the subject and predicate devices.

Sofsilk™ Coated Braided Silk Suture has been evaluated and found compliant with the following standards:

- International standard, ISO 10993-1:2018 "Biological evaluation of medical devices-Part 1: Evaluation and testing",
- Food and Drug Administration (FDA, USA) "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", issued September 8, 2023,

Performance data: The performance of the subject Sofsilk™ Coated Braided Silk Suture has been evaluated through bench tests. The following finished product physical and mechanical performance tests were conducted: USP/EP diameter, USP needle attachment, and USP tensile strength were tested, and it was found that the subject Sofsilk™ Coated Braided Silk Suture performed equivalently to the predicate and currently marketed Sofsilk™ Coated Braided Silk Suture. Both subject and predicate sutures meet or exceed requirements of U.S.P. Stability Studies were conducted, and the proposed device shelf life was demonstrated.

Biocompatibility evaluation was performed and confirmed that Sofsilk™ Coated Braided Silk Suture is compliant with ISO Standard 10993-1 for its intended patient contact profile.
This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion: The evidence and testing demonstrate that the subject Sofsilk™ Coated Braided Silk Suture with new mordant and sterilization method is substantially equivalent to the predicate Sofsilk™ Coated Braided Silk Suture (K980124).