January 12, 2024

Cypris Medical
% Erin Gontang
Senior Consultant
Rqm+
2251 San Diego Avenue
B-257
San Diego, California 92110

Re: K233355
Trade/Device Name: Cypris eXact Suturing System
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW, GAW, NBY, GEJ
Dated: September 29, 2023
Received: September 29, 2023

Dear Erin Gontang:

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.

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,

Yu-chieh Chiu -S

for Tek Lamichhane
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233355

Device Name
Cypris eXact Suturing System

Indications for Use *(Describe)*

Cypris eXact Suture PP (Polypropylene)
The Cypris eXact Suture (PP) is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Cypris eXact Suture PTFE (Polytetraflouroethylene)
The Cypris eXact Suture (PTFE) is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries.

Cypris eXact Suture PDO (Polydioxanone)
The Cypris eXact Suture (PDO) is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

The Cypris eXact 5.1 Suture Placement Device can be used in conjunction with eXact Sutures, which are indicated for use in general 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.

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510(k) SUMMARY

DATE PREPARED
January 12, 2024

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DEVICE INFORMATION

Trade/Proprietary Name	Cypris eXact Suturing System	
Common Name	Suturing System	
Regulatory Class:	II	
Regulation Number/Name:	878.4840	Absorbable polydioxanone surgical suture
	878.5010	Nonabsorbable polypropylene surgical suture
	878.5035	Nonabsorbable expanded polytetrafluoroethylene surgical suture
	878.4800	Manual surgical instrument for general use
Product Code:	NEW	
	GAW	
	NBY	
	GEJ	
Classification Panel	General & Plastic Surgery	
Premarket Review	Office of Health Technology 4 (Surgical and Infection Control Devices) Division of Health Technology 4B (Infection Control and Plastic and Reconstructive Surgery)	

PREDICATE DEVICE IDENTIFICATION

The Cypris eXact Suturing System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K131224	Sharpoint Polypropylene Surgical Suture, LOOK Polypropylene Surgical Suture, Quill Polypropylene Knotless Tissue-Closure / Surgical Specialties Corp.	✓
K160744	LOOK PTFE Suture / Surgical Specialties Corp.	
K063680	Sharpoint PDO (polydioxanone) Sutures / Surgical Specialties Corp.	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The Cypris eXact Suturing System is comprised of the Cypris eXact Suture and the Cypris eXact 5.1 Suture Placement Device. The Cypris eXact Suture and the Cypris eXact 5.1 Suture Placement Device are for use in general soft tissue approximation by surgeons, are single-use, and are provided sterile.

The Cypris eXact Suture is a synthetic, monofilament suture available in three different materials: polypropylene (PP), polydioxanone (PDO), and polytetraflouroethylene (PTFE). The Cypris eXact Suture (PP) is a non-absorbable, sterile surgical suture available in two sizes, USP sizes 3-0 and 4-0. The Cypris eXact Suture (PTFE) is a non-absorbable, sterile surgical suture available in two sizes, USP sizes 2-0 and 3-0. The Cypris eXact Suture (PDO) is an absorbable, sterile surgical suture available in two sizes, USP sizes 3-0 and 4-0. Each 24-inch suture has a stainless-steel BB needle attached to one end of the suture.

Cypris eXact Sutures can be used with the Cypris eXact 5.1 Suture Placement Device, a hand-held device used for the placement of a surgical suture.

INDICATIONS FOR USE

Cypris eXact Suture PP (Polypropylene)
The Cypris eXact Suture (PP) is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Cypris eXact Suture PTFE (Polytetraflouroethylene)
The Cypris eXact Suture (PTFE) is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries.

Cypris eXact Suture PDO (Polydioxanone)
The Cypris eXact Suture (PDO) is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

The Cypris eXact 5.1 Suture Placement Device can be used in conjunction with eXact Sutures, which are indicated for use in general soft tissue approximation and/or ligation.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Cypris Medical believes that the Cypris eXact Suturing System is substantially equivalent to the predicate devices based on the information summarized here:

The Cypris eXact Sutures are equivalent to original equipment manufacturer (OEM) sutures currently produced under the Sharpoint (K131224 and K063680) and LOOK (K160744) brands. The Cypris eXact Suturing System sutures are identical in their final finished form in formulation, processing, sterilization, and geometry to the sutures previously cleared in K131224, K063680, and K160744. Given the Cypris eXact Sutures are identical to the predicate device, share the same intended use, and have equivalent technological performance characteristics, the Cypris eXact Sutures are considered substantially equivalent to the predicates.

SUBSTANTIAL EQUIVALENCE

The Cypris eXact Suture - PP (Polypropylene) is substantially equivalent in intended use and fundamental scientific technology as the Sharpoint Polypropylene Surgical Suture, LOOK Polypropylene Surgical Suture, Quill Polypropylene Knotless Tissue-Closure cleared under K131224 (May 16, 2013). The substantial equivalence table for the comparison of the subject and predicate device is provided below.

	Subject Device	***Predicate Device***
	Cypris Medical, Inc. Cypris eXact Suture - PP (Polypropylene) K233355	Surgical Specialties Corp. Sharpoint Polypropylene Surgical Suture, LOOK Polypropylene Surgical Suture, Quill Polypropylene Knotless Tissue-Closure K131224
Indications for Use	The Cypris eXact Suture (PP) is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Polypropylene suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Regulation Number	21 CFR 878.5010	21 CFR 878.5010
Regulation Description	Nonabsorbable polypropylene surgical suture	Nonabsorbable polypropylene surgical suture
Product Code/Name	GAW - Suture, Nonabsorbable, Synthetic, Polypropylene	GAW - Suture, Nonabsorbable, Synthetic, Polypropylene
Materials	Polypropylene Suture Stainless Steel Needle	Polypropylene Suture Stainless Steel Needle
Suture Construction	Monofilament	Monofilament
Suture Colorant	Phthalocyaninato (2-) Copper	Phthalocyaninato (2-) Copper
Suture Size(s)	USP sizes 3-0 and 4-0	USP sizes 3-0 and 4-0
Suture Diameter	All suture sizes meet USP <861> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <861> requirements for nonabsorbable surgical sutures
Suture Tensile Strength	All suture sizes meet USP <881> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <881> requirements for nonabsorbable surgical sutures
Needle Attachment Strength	All suture sizes meet USP <871> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <871> requirements for nonabsorbable surgical sutures
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Biocompatibility	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.

Cypris eXact Suture - PTFE (Polytetraflouroethylene) is substantially equivalent in intended use and fundamental scientific technology as the LOOK PTFE Suture cleared in K160744 (July 13, 2016). The substantial equivalence table for the comparison of the subject and predicate device is provided below.

	Subject Device	***Predicate Device***
	Cypris Medical, Inc. Cypris eXact Suture - PTFE (Polytetraflouroethylene) K233355	Surgical Specialties Corp. LOOK PTFE Suture K160744
Indications for Use	The Cypris eXact Suture (PTFE) is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries.	PTFE (polytetrafluoroethylene) suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries.
Regulation Number	21 CFR 878.5035	21 CFR 878.5035
Regulation Description	Nonabsorbable expanded polytetrafluoroethylene surgical suture	Nonabsorbable expanded polytetrafluoroethylene surgical suture
Product Code/Name	NBY - Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene	NBY - Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene
Materials	Polytetraflouroethylene Suture Stainless Steel Needle	Polytetraflouroethylene Suture Stainless Steel Needle
Suture Construction	Monofilament	Monofilament
Suture Colorant	None	None
Suture Size(s)	USP sizes 2-0 and 3-0	USP sizes 2-0 and 3-0
Suture Diameter	All suture sizes meet USP <861> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <861> requirements for nonabsorbable surgical sutures
Suture Tensile Strength	All suture sizes meet USP <881> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <881> requirements for nonabsorbable surgical sutures
Needle Attachment Strength	All suture sizes meet USP <871> requirements for nonabsorbable surgical sutures	All suture sizes meet USP <871> requirements for nonabsorbable surgical sutures
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Biocompatibility	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.

Cypris eXact Suture - PDO (Polydioxanone) is substantially equivalent in intended use and fundamental scientific technology as the Sharpoint PDO (polydioxanone) Sutures cleared in K063680 (May 9, 2007). The substantial equivalence table for the comparison of the subject and predicate device is provided below.

	Subject Device	***Predicate Device***
	Cypris Medical, Inc. Cypris eXact Suture - PDO (Polydioxanone) K233355	Surgical Specialties Corp. Sharpoint PDO (polydioxanone) Sutures K063680
Indications for Use	The Cypris eXact Suture (PDO) is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.	Sharpoint PDO sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular, or neurological tissues, microsurgery or ophthalmic surgery.
Regulation Number	21 CFR 878.4840	21 CFR 878.4840
Regulation Description	Absorbable polydioxanone surgical suture	Absorbable polydioxanone surgical suture
Product Code/Name	NEW - Suture, Surgical, Absorbable, Polydioxanone	NEW - Suture, Surgical, Absorbable, Polydioxanone
Materials	Polydioxanone Suture Stainless Steel Needle	Polydioxanone Suture Stainless Steel Needle
Suture Construction	Monofilament	Monofilament
Suture Colorant	D&C No.2	D&C No.2
Suture Size(s)	USP sizes 3-0 and 4-0	USP sizes 3-0 and 4-0
Suture Diameter	All suture sizes meet USP <861> requirements for absorbable surgical sutures	All suture sizes meet USP <861> requirements for absorbable surgical sutures
Suture Tensile Strength	All suture sizes meet USP <881> requirements for absorbable surgical sutures	All suture sizes meet USP <881> requirements for absorbable surgical sutures
Needle Attachment Strength	All suture sizes meet USP <871> requirements for absorbable surgical sutures	All suture sizes meet USP <871> requirements for absorbable surgical sutures
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Biocompatibility	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.	Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute and Subchronic Toxicity, Chronic Toxicity, Genotoxicity, Carcinogenicity, and Implantation.

SUMMARY OF NON-CLINICAL TESTING

The Cypris eXact Sutures were tested in accordance with the requirements of USP - absorbable and non-absorbable surgical sutures for suture diameter, tensile strength, and needle attachment, and meet the requirements of the *Guidance for Industry and FDA Staff: Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff* (issued June 3, 2003). The Cypris eXact 5.1 Suture Placement Device was tested to evaluate the integrity of the sterile barrier and the functionality of the device following 3 years of real-time aging. While the shelf-life of the Cypris eXact 5.1 Suture Placement Device is 3 years, the Cypris eXact Sutures have a shelf-life of 5 years.

All materials used in the fabrication of the Cypris eXact Sutures were evaluated through biocompatibility testing as outlined in ISO 10993-1:2018 – *Biological Evaluation of Medical Devices – Part I: Evaluation and Testing* for an implanted device with Long Term (> 30 days) contact with tissue. The following biocompatibility endpoints were evaluated for the Cypris eXact Sutures: cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute and subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, and implantation. The Cypris eXact 5.1 Suture Placement Device underwent biocompatibility testing as an external communicating device with limited contact (≤24 hours) with tissue. The following biocompatibility endpoints were evaluated for the Cypris eXact 5.1 Suture Placement Device: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity.

CONCLUSION

The Cypris eXact Sutures are substantially equivalent to the predicate devices because there are no differences in technological or performance characteristics between them. Biocompatibility data and the results of performance testing also demonstrate the substantial equivalence of the Cypris eXact Sutures to that of the predicate devices. Furthermore, the Cypris eXact Sutures demonstrate conformance with the USP, ISO, and FDA's Guidance for Surgical Sutures. The Cypris eXact Sutures can be used with the Cypris eXact 5.1 Suture Placement Device.

The Cypris eXact Suturing System is considered substantially equivalent to the predicate devices based on the testing performed, same intended use, and identical technological characteristics. The subject device does not raise new issues of safety or performance compared to the predicate devices.