May 3, 2024

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

Re: K240185
Trade/Device Name: Cypris eXact Suture Placement Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class I
Product Code: GEJ
Dated: January 23, 2024
Received: January 23, 2024

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
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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)*
K240185

Device Name
Cypris eXact Suture Placement Device

Indications for Use *(Describe)*
The Cypris eXact Suture Placement Device is indicated for use in general soft tissue approximation when used with sutures.

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
K240185

DATE PREPARED
May 1, 2024

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DEVICE INFORMATION

Trade/Proprietary Name	Cypris eXact Suture Placement Device
Common Name	Suture Placement Device
Regulatory Class:	I
Regulation Number/Name:	21 CFR 878.4800/Manual Surgical Instrument for General Use
Product Code:	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 Suture Placement Device is substantially equivalent to the following:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate/Reference*
Class I, 510(k) Exempt	Cypris eXact 5.1 Suture Placement Device / Cypris Medical, Inc.	Primary Predicate
K233355	Cypris eXact Suturing System / Cypris Medical, Inc.	Reference Device
K994290	Bard Endoscopic Suturing System / C.R. Bard, Inc.	Reference Device

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

DEVICE DESCRIPTION

The Cypris eXact Suture Placement Device is for use in general soft tissue approximation by surgeons, and it is single-use and provided sterile. It is a hand-held device used for the placement of a surgical suture, and the device consists of a handle, needle driver, and tissue capture port. The handle is designed for manual manipulation of the suture placement device, allowing the surgeon to advance the device to the desired deployment site. The needle driver functions to pass the suture when it is advanced and retracted. The tissue capture port consists of a capture chamber, needle, and hook assembly, and holds the tissue to be sutured during either manual palpation or vacuum-assisted palpation of tissue into the tissue capture port. Suture placement is achieved by advancing and retracting the needle driver.

INDICATIONS FOR USE

> *The Cypris eXact Suture Placement Device is indicated for use in general soft tissue approximation when used with sutures.*

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Cypris Medical believes the Cypris eXact Suture Placement Device is substantially equivalent to the primary predicate device based on the information summarized here:

The Cypris eXact Suture Placement Device has the same intended use as the primary predicate device, and they are identical with respect to formulation, processing, and sterilization. The difference between the subject and predicate devices is that the Cypris eXact Suture Placement Device is packaged with a vacuum connector, which gives the user the option of connecting the suture placement device to a vacuum source.

SUBSTANTIAL EQUIVALENCE

The Cypris eXact Suture Placement Device is substantially equivalent to the primary predicate device in its intended use, as well as formulation, processing, and sterilization. The substantial equivalence table for the comparison of the subject and predicate devices is provided below.

	Subject Device	***Predicate Device***
	Cypris Medical, Inc. Cypris eXact Suture Placement Device K240185	Cypris Medical, Inc. Cypris eXact 5.1 Suture Placement Device Class I (510(k) Exempt)
Indications for Use	The Cypris eXact Suture Placement Device is indicated for use in general soft tissue approximation when used with sutures.	The Cypris eXact 5.1 Suture Placement Device is indicated for use in general soft tissue approximation.
Regulation Number	21 CFR 878.4800	21 CFR 878.4800
Regulation Description	Manual Surgical Instrument for General Use	Manual Surgical Instrument for General Use
Product Code/Name	GEJ / Carrier, Ligature	GEJ / Carrier, Ligature
Classification	Class I	Class I
510(k) Exempt	No	Yes
Device Description	The Cypris eXact Suture Placement Device is for use in general soft tissue approximation by surgeons, is single-use, and is provided sterile. It is a hand-held device used for the placement of a surgical suture, and the device consists of a handle, needle driver, and tissue capture port.	The Cypris eXact Suture Placement Device is for use in general soft tissue approximation by surgeons, is single-use, and is provided sterile. It is a hand-held device used for the placement of a surgical suture, and the device consists of a handle, needle driver, and tissue capture port.
Intended Use	General Soft Tissue Approximation	General Soft Tissue Approximation
Device Materials	Polycarbonate Stainless Steel	Polycarbonate Stainless Steel
Single Use Device	Yes	Yes
Tissue Capture Method	Manual Palpation Vacuum-Assisted Palpation	Manual Palpation
Suture Deployment	The suture is threaded into needle proximal of tissue capture port. When deployed, the needle passes through tissue, pushing the suture through the tissue. The suture is captured in the distal end of the device, and then the needle is retracted	The suture is threaded into needle proximal of tissue capture port. When deployed, the needle passes through tissue, pushing the suture through the tissue. The suture is captured in the distal end of the device, and then the needle is retracted
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Biocompatibility	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity

The named reference devices provided additional information to help substantiate the safety and effectiveness of the subject device and the use of vacuum-assisted palpation. Information about both reference devices is provided below.

	Reference Device	***Reference Device***
	Cypris Medical, Inc. Cypris eXact Suturing System K233355	C.R. Bard, Inc. Bard Endoscopic Suturing System K994290
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.	For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic Gastroesophageal Reflux Disease.
Regulation Number	21 CFR 878.4840 21 CFR 878.5010 21 CFR 878.5035 21 CFR 878.4800	21 CFR 876.1500
Regulation Description	Absorbable polydioxanone surgical suture Nonabsorbable polypropylene surgical suture Nonabsorbable expanded polytetrafluoroethylene surgical suture Manual Surgical Instrument for General Use	Endoscope and Accessories
Product Code/Name	NEW / Suture, Surgical, Absorbable, Polydioxanone GAW / Suture, Nonabsorbable, Synthetic, Polypropylene NBY / Suture, Surgical, Nonabsorbable, Expanded, PTFE GEJ / Carrier, Ligature	ODE / Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (GERD)
Classification	Class II	Class II
510(k) Exempt	No	No
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	The Bard Endoscopic Suturing System consists of a capsule assembly with suction tubing and a fixed head knot pusher that attaches to the distal end of a flexible endoscope or a through-the-scope knot

	use in general soft tissue approximation by surgeons, are single-use, and are provided sterile.	pusher, plus a needle assembly, pusher wire, guidewire and suture cutter that all pass through an endoscope's biopsy channel.
Intended Use	General Soft Tissue Approximation	Place Stitches and Tie Suture Material to Approximate Soft Tissue Under Endoscopic Visualization
Device Materials	Polycarbonate Stainless Steel	Plastic Stainless Steel
Single Use Device	Yes	Yes
Tissue Capture Method	Manual Palpation	Vacuum-Assisted Palpation
Suture Deployment	The suture is threaded into needle proximal of tissue capture port. When deployed, the needle passes through tissue, pushing the suture through the tissue. The suture is captured in the distal end of the device, and then the needle is retracted	The handle assembly is manually activated, advancing the needle through the tissue, at which time the suture tag is pushed through the needle assembly by the pusher wire until the suture tag exits the needle and is captured within the end cap of the capsule assembly. The handle and needle are then retracted.
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Biocompatibility	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity

SUMMARY OF NON-CLINICAL TESTING

The Cypris eXact Suture Placement Device underwent biocompatibility testing as an external communicating device with limited contact (≤24 hours) with tissue. The following biocompatibility endpoints were evaluated: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity.

The Cypris eXact 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. The shelf-life of the Cypris eXact Suture Placement Device is 3 years.

Performance testing of the Cypris eXact Suture Placement Device and a comprehensive vacuum safety evaluation were completed. Testing demonstrated that the subject device performs as expected and that the use of vacuum-assisted palpation is equivalent to the use of manual palpation by the predicate device. Peak suction force was measured at a vacuum level of 25.0 inHg, a likely vacuum level used in clinical settings. At this vacuum level, the minimum, maximum, and average measured peak suction force achieved by the Cypris eXact Suture Placement Device was 0.753 lbf, 1.052 lbf, and 0.904 lbf, respectively.

CONCLUSION

Based on the totality of evidence, including performance testing and a comprehensive vacuum safety evaluation, Cypris Medical concluded that use of vacuum-assisted palpation with the subject device does not raise different questions of safety and effectiveness relative to the predicate device. The Cypris eXact Suture Placement Device is determined to be substantially equivalent to the predicate device.