June 24, 2021

LSI Solutions, Inc.
Christopher Miller
Executive Director of Regulatory Affairs and Quality
7796 Victor-Mendon Road
Victor, New York 14564

Re: K202551
Trade/Device Name: Cor-Knot Micro
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 2, 2020
Received: September 3, 2020

Dear Mr. Miller:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202551

Device Name
COR-KNOT MICRO™

Indications for Use *(Describe)*
The COR-KNOT MICRO™ device with COR-KNOT MICRO™ fastener when used in conjunction with USP 6-0, 7-0, or 8-0 polypropylene surgical suture, is indicated for use in the approximation of soft tissue.

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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Section 5: 510(k) Summary

Submitted By: LSI SOLUTIONS, Inc.

7796 Victor-Mendon Road

Victor, NY 14564

Contact Person: Christopher B. Miller

Executive Director of Regulatory Affairs and Quality

Phone: (585) 869-6665

Fax: (585) 742-8086

Email: cmiller@lsisolutions.com

Date Prepared: September 2, 2020 (updated June 23, 2021)

Trade Name: COR-KNOT MICRO™

Common Name: Knot tying device

Classification Name: Accessory to an endoscope (per 21 CFR 876.1500); and

Manual Surgical Instrument for General Use (per 21 CFR 878.4800)

Classification Regulation: 21 CFR 876.1500 (Per the higher classification)

Product Code: GCJ (which is reviewed by the General and Plastic Surgery Panel)

Device Classification: Class II

Predicate Device: TK® Ti-KNOT® Device

Device Description

The COR-KNOT MICRO™ Device is a sterile, single patient use device provided to the user preloaded with a single COR-KNOT MICRO™ fastener. Made from medical grade titanium, the COR-KNOT MICRO™ fastener is a hollow sleeve with a rounded base. A white plastic target holds the loop shape of a wire snare. The wire snare passes through the COR-KNOT MICRO™ fastener and is attached to a snare puller knob. A suture slot in the device shaft lies under the opening in the snare puller. The ends of a USP 6-0, 7-0, or 8-0 polypropylene suture are passed through the wire snare and subsequently threaded into the titanium fastener. The snare puller attached to its wire snare is pulled up along the device shaft until it snaps onto the puller retainer feature of the purple knob, which also has an integrated indicator fin. The suture slot and the indicator fin are located on the same side of the device shaft. The subsequently crimped fastener and remnant trimmed suture tails bend slightly in the direction away from or opposite from the suture slot and indicator fin. By rotating the purple knob and the device's white handle, the surgeon can ergonomically orient the direction of the suture tails, if desired. A yellow lever stop is located behind the purple lever to restrict inadvertent squeezing of the lever during device handling before crimping. The lever stop is removed by pinching its sides together and pulling it out of the handle. By squeezing the purple lever, the COR-KNOT MICRO™ Device crimps the

COR-KNOT MICRO™ fastener to fasten together segments of suture and trims away excess suture.

One COR-KNOT MICRO™ Device is provided per package, and the COR-KNOT MICRO™ Device is not intended to be reloaded or reused.

The COR-KNOT MICRO™ device is intended for use in the approximation of soft tissue.

Indications for Use

The COR-KNOT MICRO™ device with COR-KNOT MICRO™ fastener when used in conjunction with USP 6-0, 7-0, or 8-0 polypropylene surgical suture, is indicated for use in the approximation of soft tissue.

Technological characteristics (comparison to Predicate Device)

Both the predicate Ti-KNOT® device and the subject COR-KNOT MICRO™ device have the same intended use: "Intended for use in the approximation of soft tissue." The predicate Ti-KNOT® device is "indicated for use in the approximation of soft tissue", and LSI recommends its use with 2-0 polypropylene suture, among other suture types. The subject COR-KNOT MICRO™ device has very similar indications. The COR-KNOT MICRO™ device, when used with USP 6-0, 7-0, and 8-0 polypropylene suture is also "indicated for use in the approximation of soft tissue." While the predicate and subject devices are each optimized for securing different types of suture, they operate on identical technical principles. Both devices are single use, non-powered, hand operated devices which incorporate a hammer-anvil mechanism that crimps a

titanium fastener held in the device tip onto suture previously snared through the fastener. Both devices also trim away excess suture tails.

Knot pull apart (KPA) force is a key performance requirement for both subject and predicate devices. Both the predicate Ti-KNOT® device and the subject COR-KNOT MICRO™ device exceed the USP KPA specifications for their compatible suture. Both the predicate and subject devices are provided sterile and are sterilized with Ethylene Oxide such that a minimum lethality of 10^{-6} is achieved. The predicate Ti-KNOT® device is a stainless steel and polymer delivery device with a titanium fastener. The COR-KNOT MICRO™ device is made from identical materials for the delivery device and the fastener. Both devices conform to the requirements of ISO 10993. The predicate device is packaged in a rigid thermoformed blister tray with a Tyvek cover. The subject device is comparably packaged in a PETG tray and snap retainer lid that is sealed in a Tyvek/nylon pouch.

The COR-KNOT MICRO™ device and the predicate Ti-KNOT® device are substantially equivalent. The differences between the subject and predicate devices are largely related to size, their function is comparable, and the differences do not introduce any new risks and have no negative impact on the safety and efficacy of the device.

Performance Testing Summary

Bench top performance testing was conducted to verify that the COR-KNOT MICRO™ device will perform as intended and to ensure the device will perform equivalently to the predicate

device. The following non-clinical tests were conducted, and all results met the performance and risk-based acceptance criteria:

- Functional Verification and Validation Testing to ensure the following Design Input Requirements were met:
  - Fastener must secure 6-0, 7-0 and 8-0 polypropylene suture with knot pull apart (KPA) forces exceeding USP standards.
  - Fastener shall not be damaged prior to deployment.
  - Device shall retain fastener prior to crimping/cutting without the fastener dislodging from the tip of the device.
  - Releasing the crimped fastener from the device, shall not damage the fastener.
  - The device shall cut the suture after a completed crimp.
  - Crimped fastener shall not cause more damage to anatomy than hand tied suture/knots.
  - The device shall be compatible with only COR-KNOT MICRO™ fasteners.
  - System compatible with 6-0, 7-0, and 8-0 sized polypropylene sutures.
  - The device will prevent reloading in the field.
  - Inserted shaft length shall be comparable to other related surgical devices demonstrated to reach superficial surgical access sites and most open and minimally invasive surgical site locations.
  - Device shall allow for surgical site visibility.
  - Inserted portion of device and entirety of fastener shall be shaped to reduce risk of tissue damage or other iatrogenic injury.
  - The device and fastener must function with exposure to typical surgical conditions.

- Device must be capable of firing the single fastener provided with the device. If multiple fasteners are required within a case, multiple devices must be used.
- The device shall allow suture to be easily loaded through the titanium fastener and distal end of the device.
- The user must be able to remove Lever Stop prior to use of the device.
- The user must be able to crimp a fastener with one hand.
- The device shall not cause harm to the user.

- Biocompatibility per ISO 10993-1:2018.
- Packaging/Shelf-life Testing per ISO 11607-1 demonstrating a 3 year shelf life.

Additional bench testing involving a custom malignant hypertension pressure simulator successfully demonstrated the excellent strength and stability of COR-KNOT MICRO™ titanium fasteners on large diameter pulsatile tubular structures, mimicking extreme, supraphysiologic conditions during a simulated protracted healing period. This worst-case durability experiment incorporated supraphysiologic pressure waves mimicking systolic and diastolic pressure conditions more than 3x greater (>360/240 mmHg arterial blood pressure) than normal blood pressure in a human patient (120/80 mmHg). The pulsatile rate was also 25% faster, at 90 pulses per minute, than a normal rate, which is typical cited at 72 beats per minute. The experiment was conducted over a 6 week period to exceed the normal healing duration by a factor of 2–3x. All 60 COR-KNOT MICRO™ titanium fasteners used to secure 6-0, 7-0, and 8-0 polypropylene suture held without compromise throughout this protracted simulated healing period, despite being exposed to conditions beyond the physiologic worst case. For the duration of the six week test, all of the COR-KNOT MICRO™ titanium fasteners successfully secured simple interrupted

6-0, 7-0, and 8-0 sutures to close 8 Fr dilated wounds (consistent with the predicate device in vivo study) in simulation chambers utilizing pulsatile segments of latex tubing, which has an unpressurized diameter of 2.22 cm (7/8 in) and a wall thickness of 1.59 mm (1/16 in), to simulate aortic tissue within the human circulatory system.

The worst-case physiologic scenario in this test included several elements. The worst-case wound repair method was a simple interrupted suture, which used the lowest minimum number of strands through tissue to hold wound edges together. Thus, the force exerted on this single loop of suture, and the titanium fastener securing it, is higher than when multiple suture strands are incorporated at the same wound closure site. The worst-case suture size regarding titanium fastener holding force was the smallest diameter suture tested. The size of tissue structures routinely sutured with 6-0, 7-0, and 8-0 polypropylene is generally smaller than the human femoral artery, which is typically less than 10 mm in diameter. The worst-case tissue type was a large artery in a hypertensive patient who is tachycardic and slow to heal. The diameter of the tissue simulated in this experiment was ~30 mm. This simulation experiment also provided a sustained physiologic worst-case blood pressure of >360/240 mmHg over 6 weeks, which would be nonsurvivable in a patient. A worst-case healing time of 6 weeks was selected, which is several times greater than the 2–3 week period during which wounds would be expected to heal. Additionally, the pulsatile pattern simulating heart rate in this experiment (90 pulses per minute, ppm) was 25% more ppm than the typical human heart rate of 72 beats per minute (bpm). At a pulse rate of 90 bpm and an experimental duration of 6 weeks, 1 day, 3 hours, and 33 minutes (62,133 minutes), each wound closure experienced 5,591,970 distinct hypertensive pulses. The 60 COR-KNOT MICRO™ titanium fasteners—20 each for 6-0, 7-0, and 8-0 polypropylene

suture—experienced a total cumulative 335,518,200 distinct hypertensive pulses without any compromise.

This study confirmed that the COR-KNOT MICRO™ Device and its titanium fastener have the ability to secure and maintain closure of 6-0, 7-0, and 8-0 polypropylene suture under physiologic worst-case conditions over protracted healing time while being exposed to continuous pulsatile forces—384.6 mmHg average systolic pressure and 259.1 mmHg average diastolic pressure—beyond the stresses anticipated on the product under conditions of the clinically relevant worst-case scenario. The COR-KNOT MICRO™ Device and its titanium fastener successfully met all predetermined requirements and acceptance criteria defined for retention testing of the titanium fastener.

LSI also conducted an acute animal study to evaluate the safety and effectiveness of the proposed COR-KNOT MICRO™ Device and preloaded micro titanium fastener relative to a comparative study conducted in 1995 for the predicate device. The test report for the animal study compares the COR-KNOT MICRO™ Device in the worst-case size blood vessels to hand tied knots under the same conditions. The COR-KNOT MICRO™ titanium fastener provided superior or equivalent—and never inferior—results for ease of use, wound approximation, hemostasis, burst strength, and tensile strength as compared to the controls. Results and observations from the animal procedure tests demonstrate that the COR-KNOT MICRO™ Device with its titanium fastener is easy to use and provides excellent wound approximation resulting in hemostasis in conjunction with 6-0, 7-0, and 8-0 polypropylene suture. Overall, this study confirmed that the COR-KNOT MICRO™ Device and its titanium fastener have the ability

to hemostatically secure and maintain closure of wounds using 6-0, 7-0, and 8-0 polypropylene suture in an acute in vivo pig model; harvested specimens were tested and demonstrated burst strengths beyond supraphysiologic worst case anticipated conditions.

Clinical testing

Not applicable. Neither the predicate product nor the subject product require clinical testing since the performance of this product is to hold the suture that holds tissue (but not directly the tissue itself). The reliability and excellent performance of this product has been sufficiently demonstrated in multiple experiments that do not require clinical testing in patients.

Substantial Equivalence

The subject device and predicate device have the same intended use and technological characteristics. Non-clinical performance data has demonstrated the subject device is substantially equivalent to the predicate device.

In Conclusion

Extensive testing demonstrates the proposed COR-KNOT MICRO™ product consistently provides excellent suture holding security for 6-0, 7-0, and 8-0 polypropylene suture and can be dependably manufactured. The subject COR-KNOT MICRO™ device and titanium fastener are substantially equivalent to the predicate Ti-KNOT® device, K981531.