November 24, 2020

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

Re: K203081
Trade/Device Name: RAM COR-SUTURE QUCIK LOAD Surgical Suture
COR-SUTURE QUICK LOAD Surgical Suture
Regulation Number: 21 CFR 878.5010, 21 CFR 878.5000
Regulation Name: Nonabsorbable Polypropylene Surgical Suture, Nonabsorbable Poly(ethylene terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAW, GAS
Dated: October 10, 2020
Received: October 13, 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,

For Cindy Chowdhury, Ph.D., MBA
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203081

Device Name
RAM® COR-SUTURE® QUICK LOAD® Surgical Suture;
COR-SUTURE® QUICK LOAD® Surgical Suture

Indications for Use *(Describe)*
The RAM® COR-SUTURE® QUICK LOAD® surgical suture is indicated for use in the approximation of soft tissue and prosthetic materials.

The COR-SUTURE® QUICK LOAD® surgical suture is indicated for use in the approximation of soft tissue and prosthetic materials.

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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K203081 – Special 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
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Email: cmiller@lsisolutions.com

Date Prepared: October 10, 2020

Trade Name(s): RAM® COR-SUTURE® QUICK LOAD®
COR-SUTURE® QUICK LOAD®

Common Name: Nonabsorbable Surgical Suture

Classification Names: Nonabsorbable poly(ethylene terephthalate) surgical suture
Nonabsorbable polypropylene surgical suture

Classification Regulations: 21 CFR 878.5000 (Nonabsorbable poly(ethylene terephthalate) surgical suture)
21 CFR 878.5010 (Nonabsorbable polypropylene surgical suture)

Product Codes: GAS
GAW

Device Classification: Class II

Predicate Device

The predicate device for establishing substantial equivalence is listed in **Table 1,** below. This predicate has not been subject to any type of recall.

Table 1: Predicate Device for Subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD

Predicate Device	Manufacturer	510(k)	Clearance Date
Pledgeted COR-SUTURE™ QUICK LOAD®	LSI SOLUTIONS, Inc.	K160529	September 15, 2016

Device Description

LSI SOLUTIONS® offers both the RAM® COR-SUTURE® QUICK LOAD® surgical suture, which is a non-absorbable polytetrafluoroethylene (PTFE)-coated, braided polyester surgical suture, and the COR-SUTURE® QUICK LOAD® surgical suture, which is available as either a PTFE-coated, braided polyester surgical suture or a monofilament, uncoated polypropylene surgical suture. The RAM® COR-SUTURE® QUICK LOAD® surgical suture is also supplied with an optional pre-attached PTFE pledget that is used to aid in suture buttressing and to mechanically secure and support the suture in fragile tissue, increasing the suture holding strength. A short length of modified surgical stainless-steel tubing, called a "needle cap", is attached to each end of the suture for both the RAM® COR-SUTURE® QUICK LOAD® surgical suture and the COR-SUTURE® QUICK LOAD® surgical suture. Relative to the COR-SUTURE® QUICK LOAD® device, the RAM® COR-SUTURE® QUICK LOAD® device additionally includes a needle cap holder to secure the optional pledget and needle caps in the suture tray. Both the RAM® COR-SUTURE® QUICK LOAD® surgical suture and the COR-SUTURE® QUICK LOAD® surgical suture also include a detachable clear suture tube to keep the suture from tangling. The needle caps are removed from the sutures and discarded once suturing is completed as they are not intended for implantation in the patient; only the suture and pledget are implantable of components.

Both devices are packaged for single patient use and are provided sterile by means of a validated ethylene oxide (EO) cycle. The polyester RAM® COR-SUTURE® QUICK LOAD® surgical suture is offered undyed (white), dyed green with the FDA approved colorant D&C Green No. 6, or striped green/white; all of which are offered with a surgical suture diameter of USP size 2-0 and a length of 38 inches. The polyester COR-SUTURE® QUICK LOAD® surgical suture is available

undyed (white) or dyed green with the FDA approved colorant D&C Green No. 6 and will be offered with a surgical suture diameter of USP size 2-0 and a length of 38 inches. The polypropylene COR-SUTURE® QUICK LOAD® surgical suture is dyed blue with the FDA approved colorant [phthalocyaninato(2-)] copper and will be offered with a surgical suture diameter of USP size 3-0 and a length of 53 inches. For both polypropylene and polyester suture, there is no known significant change in tensile strength retention to occur *in vivo*. The RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures, with needle caps removed, contains implantable components which are considered MR safe. The implantable polyester and polypropylene sutures and PTFE pledget material are non-metallic and non-conducting materials and therefore, considered MR safe.

Intended Use

The intended use remains the same as the predicate device, and both the subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures are intended for the approximation of soft tissue and prosthetic materials.

The indications for use remains the same as that of the predicate device, and both the subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures are indicated for use in the approximation of soft tissue and prosthetic materials.

Technological Characteristics (comparison to Predicate Device)

The subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures are substantially equivalent in intended use and fundamental technological characteristics to the predicate device. Both the subject and predicate devices are non-absorbable surgical suture available as either uncoated monofilament polypropylene (diameter of USP size 3-0) or PTFE-coated, braided polyester suture (diameter of USP size 2-0). Both the subject and predicate devices have a needle cap attached to each end of the suture component to facilitate use with LSI SOLUTIONS® suture placement devices. The only significant difference between the subject and predicate devices is that the subject devices utilize different raw material sources for the polyester fibers and PTFE coating of the OEM PTFE-coated, braided polyester surgical suture and a different polypropylene resin source for the OEM uncoated polypropylene suture supplied

directly from the manufacturer, Teleflex® Medical OEM. The chemical composition of these raw materials, however, remain the same.

The subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures are packaged, sterilized, and labeled in a manner substantially equivalent to the predicate device, including labeling claims such as indications, contraindications, warnings, and precautions. The subject devices are considered substantially equivalent and have the same technological characteristics to the predicate device through comparison in design, intended use, material chemical composition, function, and size range.

Non-Clinical Performance Testing Summary

Benchtop Testing

As recommended by the FDA Guidance for Industry, *Class II Special Control Guidance Document: Surgical Sutures; Guidance for Industry and FDA, June 3, 2003*, the subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures were subject to the requirements of the United States Pharmacopeia (USP), *Monograph for Non-Absorbable Sutures*. Performance testing focused on sections from the USP General Chapter on Physical Tests.

These were the same requirements and test methods used in the assessment of the predicate devices. The subject RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures continue to conform to these requirements.

Biocompatibility Testing

Biocompatibility evaluation was conducted in accordance with ANSI AAMI ISO 10993-1:2009/(R)2013 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* and the FDA Guidance for Industry, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Attachment A: Evaluation Endpoints for Consideration, September 4,2020*, to demonstrate that the RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures' patient contacting materials are substantially equivalent to the predicate

device. The RAM® COR-SUTURE® QUICK LOAD® and COR-SUTURE® QUICK LOAD® surgical sutures are classified as permanent contact duration devices that will be implanted and will have contact with blood, which is identical to the classification of the predicate device. Biocompatibility results from Teleflex® Medical OEM were leveraged and all appropriate biological endpoints for consideration per ISO 10993-1 were assessed with passing results.

Substantial Equivalence

We believe that the predicate and the subject devices have been demonstrated to be substantially equivalent. Although the raw material sources used in the OEM PTFE-coated, braided polyester surgical suture and the OEM uncoated polypropylene surgical suture have changed, their material chemical composition and design remain the same. The indications for use and fundamental scientific technology remains the same. Both the subject and the predicate devices are indicated for use in the "approximation of soft tissue and prosthetic materials", and there are no changes to the devices' chemical composition of raw materials. Biocompatibility and benchtop performance testing were conducted to evaluate all risks associated with the raw material change, and a risk analysis demonstrates there are no new risks and no negative impacts to the safety and effectiveness of the surgical suture. Therefore, the subject RAM® COR-SUTURE® QUICK LOAD® and the COR-SUTURE® QUICK LOAD® surgical sutures are substantially equivalent to the predicate LSI SOLUTIONS® Pledgeted COR-SUTURE® QUICK LOAD® suture, which was cleared in 510(k) Premarket Notification K160529 on September 15, 2016.