November 24, 2020

LSI Solutions, Inc.
Christopher Miller
Executive Director of Regulatory Affairs and Quality
7796 Victor-Mendon Road
Victor, New York 14589

Re: K203120
Trade/Device Name: RD QUICK LOAD SUTURE, 0 Polyester
RD QUICK LOAD SUTURE, 2-0 Polyester
RD QUCIK LOAD SUTURE, 2-0 Polypropylene
Regulation Number: 21 CFR 878.5000
21 CFR 878.5010
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAS, GAW
Dated: October 14, 2020
Received: October 16, 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)*
K203120

Device Name
RD® QUICK LOAD® SUTURE, 0 Polyester
RD® QUICK LOAD® SUTURE, 2-0 Polyester
RD® QUICK LOAD® SUTURE, 2-0 Polypropylene

Indications for Use *(Describe)*
The RD® QUICK LOAD® suture is intended 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K203120 – Special 510(k) Summary

Submitted By: LSI SOLUTIONS®, Inc.
7796 Victor-Mendon Road
Victor, NY 14564

Contact Person: Chris Miller
Executive Director of Regulatory Affairs and Quality
Phone: (585) 869-6665
Fax: (585) 742-8086
Email: cmiller@lsisolutions.com

Date Prepared: October 14, 2020

Trade Name: RD® QUICK LOAD® SUTURE, 0 Polyester
RD® QUICK LOAD® SUTURE, 2-0 Polyester
RD® QUICK LOAD® SUTURE, 2-0 Polypropylene

Common Name: Nonabsorbable Surgical Suture

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

Product Codes: GAS
GAW

Device Classification: Class II

Predicate Device

The predicate devices for establishing substantial equivalence are LSI SOLUTIONS® Suture QUICK LOAD® Products, including *SEW-RIGHT® QUICK LOAD®* with 0 Polyester, *SEW-RIGHT® QUICK LOAD®* with 2-0 Polyester and *SEW-RIGHT® QUICK LOAD®* with 2-0 Polypropylene, which was cleared in 510(k) Premarket Notification K031443 on June 18, 2003. The predicate device will herein be referred to as *SEW-RIGHT® QUICK LOAD®* suture. This predicate has not been subject to a design-related recall. The predicate device includes the models described in **Table 1**.

Table 1: Predicate Device Models Included Under K031443 LSI SOLUTIONS® Suture QUICK LOAD® Products

510(k)	Clearance Date	Manufacturer	Predicate Device
K031443	June 18, 2003	LSI SOLUTIONS®	*SEW-RIGHT® QUICK LOAD®* with 0 Polyester
K031443	June 18, 2003	LSI SOLUTIONS®	*SEW-RIGHT® QUICK LOAD®* with 2-0 Polyester
K031443	June 18, 2003	LSI SOLUTIONS®	*SEW-RIGHT® QUICK LOAD®* with 2-0 Polypropylene

Device Description

LSI SOLUTIONS® RD® QUICK LOAD® SUTURE is a non-absorbable surgical suture available as monofilament polypropylene suture (diameter of USP size 2-0) and polytetrafluoroethylene (PTFE)-coated, braided polyester suture (diameter of USP sizes 0 and 2-0). A short length of surgical stainless-steel tubing, called a "needle cap," is attached to one end of the suture. The needle cap is removed from the suture after suturing is completed and not meant for implantation into the patient. The RD® QUICK LOAD® SUTURE includes a detachable clear suture tube to keep the suture from tangling. The RD® QUICK LOAD® SUTURE is packaged for single patient use and is provided sterile by means of a validated ethylene oxide (EO) cycle. The polypropylene suture is dyed blue with the FDA approved colorant [phthalocyaninato(2-)] copper and will be offered with a surgical suture diameter of USP size 2-0 and in a length of 53 inches. The polyester suture is offered dyed green with the FDA approved colorant D&C Green No. 6 and is offered in a surgical suture diameter of USP size of 0 and 2-0 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 RD® QUICK LOAD® SUTURE products, with needle caps removed, contain implantable components which are considered MR (magnetic resonance) safe. The implantable polyester and polypropylene suture materials are non-metallic and non-conducting materials and therefore, considered MR safe.

Intended Use

The RD® QUICK LOAD® SUTURE products intended use statement is identical to that of the predicate device. The RD® QUICK LOAD® SUTURE products are intended for use in general soft tissue approximation and/or ligation.

The indications for use remains the same as that of the predicate device, and the subject RD® QUICK LOAD® SUTURE products are indicated for use in general soft tissue approximation and/or ligation.

Technological Characteristics (comparison to Predicate Device)

The RD® QUICK LOAD® SUTURE products are substantially equivalent in intended use and fundamental technological characteristics to the predicate device. Both the subject and predicate device are non-absorbable surgical suture available as either monofilament polypropylene (diameter of USP size 2-0) or PTFE-coated, braided polyester (diameter of USP sizes 0 and 2-0). The only significant difference between the subject device and the predicate device is that the subject device utilizes a different raw material source for the polyester fibers and PTFE coating of the OEM PTFE-coated, braided polyester surgical suture and a different polypropylene resin for the OEM polypropylene suture supplied directly from the manufacturer, Teleflex®. The chemical composition of these raw materials, however, remain the same.

The RD® QUICK LOAD® SUTURE is 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 device is considered substantially equivalent and has 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 RD® QUICK LOAD® SUTURE was subject to the requirements of the United States Pharmacopeia (USP) 42-NF37:2019 *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 device. The RD® QUICK LOAD® SUTURE continues to conform to these requirements.

Biocompatibility Testing

Biocompatibility evaluation was conducted in accordance with ISO 10993-1:2009(R)2013 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* [Rec. Number *2-220*] 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, June 16, 2016*, to demonstrate that the RD® QUICK LOAD® SUTURE patient contacting materials are in compliance with ISO 10993-1 and the devices are substantially equivalent to the predicate device. The RD® QUICK LOAD® SUTURE is classified as a permanent contact duration device that will be implanted and will have contact with tissue, 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.

Clinical Testing

The technological characteristics, indications for use, manufacturing processes, and sterilization processes are the same as the predicate device, which has an established history of safe and effective clinical use and performance; therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

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 and uncoated, monofilament polypropylene surgical suture have changed, the material chemical composition and design remain the same. The indications for use and fundamental scientific technology remain the same. The RD® QUICK LOAD® SUTURE and the predicate device are indicated for use in "general soft tissue approximation and/or ligation", and there are no changes to the devices' operating principles, mechanism of action, or the chemical composition of raw materials. Biocompatibility and performance testing were conducted to evaluate all risks associated with the device modification, 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 RD® QUICK LOAD® SUTURE is substantially equivalent to the predicate *SEW-RIGHT*® QUICK LOAD® SUTURE, which was cleared in 510(k) Premarket Notification K031443 on June 18, 2003.