DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2016

LSI Solutions
Mr. Kevin Bentley
Executive Director of Regulatory Affairs and Quality
7796 Victor-Mendon Rd
Victor, New York 14564

Re: K160529
Trade/Device Name: Pledgeted Cor-Suture Quick Load
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW, GAS
Dated: August 9, 2016
Received: August 11, 2016

Dear Mr. Bentley:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K160529

Device Name
Pledgeted COR-SUTURE™ QUICK LOAD®

Indications for Use *(Describe)*
The Pledgeted COR-SUTURE™ QUICK LOAD is intended for use in the approximation of soft tissue and prosthetic material.

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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# 510(k) SUMMARY

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

**Contact Person:** Kevin Bentley
Executive Director of Regulatory Affairs and Quality
Phone: (585) 869-6669
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**Date Prepared:** February 24, 2016

**Trade Name:** Pledgeted COR-SUTURE™ QUICK LOAD®

**Common Name:** Nonabsorbable Surgical Suture

**Classification Name:** Nonabsorbable poly(ethylene terephthalate) surgical suture
(21 CFR 878.5000, Product Code GAS)
Nonabsorbable polypropylene surgical suture
(21 CFR 878.5010, Product Code GAW)

**Device Classification:** Class II

**Predicate Device:**

The predicate device, LSI SOLUTIONS® Suture Placement Devices and Accessories, specifically the Non-Absorbable QUICK LOAD® Suture, was selected to demonstrate substantial equivalence to the Pledgeted COR-SUTURE™ QUICK LOAD®. LSI SOLUTIONS® Suture Placement Devices and Accessories was cleared in 510(k) Premarket Notification K100593 on September 24, 2010.

The Bard® PTFE Felt Pledget, which was cleared under 510(k) Premarket Notification K770835 on October 5, 1977, is used as a reference device in this submission.

**Device Description:**

Each LSI SOLUTIONS® Pledgeted COR-SUTURE™ QUICK LOAD® sterile surgical suture is held in a customized tray, with suture release feature designed to enable the rapid, easy and reliable loading of suture into compatible LSI SOLUTIONS® suturing devices. Pledgeted COR-SUTURE™ QUICK LOAD® suture is available as a non-absorbable monofilament polypropylene and PTFE coated, braided, polyester surgical suture with attached PTFE pledget. A short length of modified surgical stainless steel tubing, called a "ferrule", is attached to each end of the suture. The Pledgeted COR-SUTURE™ QUICK LOAD® suture also includes a detachable clear suture tube to keep the suture from tangling. Pledgeted COR-SUTURE™ QUICK LOAD® surgical suture is packaged for single patient use. The polypropylene suture is dyed blue with the FDA approved colorant [phthalocyaninato(2-)] copper. The polyester suture is offered undyed, or dyed green with the FDA approved colorant D&C Green No. 6. For both polypropylene and polyester suture, there is no known significant change in tensile strength retention to occur in vivo. The Pledgeted COR-SUTURE™ QUICK LOAD® surgical suture is MR safe.

**Intended Use:**

The Pledgeted COR-SUTURE™ QUICK LOAD® is intended for use in the approximation of soft tissue and prosthetic material.

The indications for use statement is identical to that of the predicate device, LSI SOLUTIONS® Suture Placement Devices and Accessories, specifically the Non-Absorbable QUICK LOAD® Suture.

**Technological Characteristics (comparison to Predicate Device):**

The Pledgeted COR-SUTURE™ QUICK LOAD® is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate device. Both the modified and predicate devices are non-absorbable surgical suture available as either monofilament polypropylene or PTFE coated, braided polyester. The Pledgeted COR-SUTURE™ QUICK LOAD® and the predicate device both have a short length of modified surgical stainless steel tubing, called a ferrule, attached to each end of the suture to facilitate use with LSI SOLUTIONS® suture placement devices. The only technological difference between the Pledgeted COR-SUTURE™ QUICK LOAD® and the predicate device is that the modified device will be packaged as surgical suture with a pledget pre-attached directly on the suture for ease of use. The pledget is composed of polytetrafluoroethylene (PTFE) and has identical material characteristics to the reference device, Bard® PTFE Felt Pledget. The modified device is packaged and sterilized in an equivalent manner and has equivalent labeling claims to the predicate device, including indications, contraindications, warnings, cautions and precautions. The modified device is considered substantially equivalent and has the same technological characteristics to its predicate device through comparison in design, intended use, material composition, function, and range of sizes.

**Performance Testing Summary:**

As recommended by the FDA Guidance for Industry, *Class II Special Control Guidance Document: Surgical Sutures; Guidance for Industry and FDA,* the Pledgeted COR-SUTURE™ QUICK LOAD® was subject to the requirements of the United States Pharmacopeia (USP) monograph for Non-Absorbable Sutures. Performance testing includes:

- *Sutures - Diameter* <861>
- *Sutures - Tensile Strength* <881>

- Ferrule Attachment which complies with the requirements for standard needle attachments as defined in USP section *Sutures – Needle Attachment* <871>.

Biocompatibility evaluation for the Pledgeted COR-SUTURE™ QUICK LOAD® was conducted in accordance with ISO 10993-1:2009: *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* and FDA 510(k) Blue Book Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration, to demonstrate that the Pledgeted COR-SUTURE™ QUICK LOAD® is substantially equivalent to the predicate device. The Pledgeted COR-SUTURE™ QUICK LOAD® is a permanent contact duration device that will be implanted in circulating blood, which is the identical type and duration of patient contact as the predicate device. Biocompatibility data has been leveraged from the manufacturer that supplies the surgical suture material to LSI SOLUTIONS®. The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Sub-chronic Toxicity and Sub-acute Toxicity
- Genotoxicity
- Implantation
- Hemocompatibility

All biocompatibility testing passed.

The Bard® PTFE Felt Pledget, which has identical material characteristics to the pledget used in the Pledgeted COR-SUTURE™ QUICK LOAD®, was tested and found biocompatible based on the materials, manufacturing processes, body contact, sterilization properties, acceptable biocompatibility test results and long clinical history of this type of use.

The Pledgeted COR-SUTURE™ QUICK LOAD® will be sterilized using a validated ethylene oxide cycle.

**Clinical Testing:**

The technological characteristics, material, manufacturing and sterilization processes are the same as the predicate device, therefore, no clinical studies were required to demonstrate the safety or effectiveness of the modified device.

**Substantial Equivalence:**

With the addition of the pledget there are no new risks introduced and no negative impact to the safety and effectiveness of the surgical suture. The indications for use remain exactly the same. Both the Non-Absorbable QUICK LOAD® Suture and the Pledgeted COR-SUTURE™ QUICK LOAD® are indicated for use in the approximation of soft tissue and prosthetic material. The Pledgeted COR-SUTURE™ QUICK LOAD® is substantially equivalent to the currently marketed LSI SOLUTIONS® Suture Placement Devices and Accessories, specifically the Non-Absorbable QUICK LOAD® Suture, cleared in 510(k) Premarket Notification K100593 on September 29, 2010.