DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2017

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

Re: K163639
Trade/Device Name: LS-5 ePTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: May 5, 2017
Received: May 9, 2017

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,

Jennifer R. Stevenson -S3

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)*

K163639

Device Name
LS-5™ ePTFE Suture

Indications for Use *(Describe)*
The LS-5™ ePTFE Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery.

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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LSI SOLUTIONS®
INNOVATIVE SOLUTIONS FOR MINIMALLY INVASIVE SURGERY

510(k) SUMMARY

Submitted By: LSI SOLUTIONS®, Inc.
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Date Prepared: May 17, 2017

Trade Name: LS-5™ ePTFE Suture

Common Name: Nonabsorbable Surgical Suture

Classification Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture (21 CFR 878.5035, Product Code NBY)

Device Classification: Class II

Predicate Device:

The predicate device, W. L. Gore and Associates Inc. GORE-TEX™ Suture ePTFE Nonabsorbable Monofilament (hereinafter known as GORE-TEX® Suture), was selected to

demonstrate substantial equivalence to the LS-5™ ePTFE Suture. GORE-TEX® Suture was initially approved under Premarket Approval Number P820083 on December 30, 1985 and was reclassified to Class II on September 9, 1999 (reference 21 CFR Part 878, Docket No. 94P-0347). The LS-5™ ePTFE Suture is designed and manufactured to be comparable to CV-5 GORE-TEX® Suture, which is designated to approximately correlate with a surgical suture diameter of USP size 2-0. The LS-5™ ePTFE Suture is also similar to CV-5 GORE-TEX® Suture for tensile strength and needle attachment. W. L. Gore and Associates Inc. promotes the CV-5 GORE-TEX® Suture as being comparable to USP size 4-0 monofilament polypropylene surgical suture.

LSI SOLUTIONS® *Suture Placement Devices and Accessories*, which was cleared under 510(k) Premarket Notification K100593 on September 24, 2010, and LSI SOLUTIONS® *Suture QUICK LOAD® Products*, which was cleared under 510(k) Premarket Notification K031443 on June 18, 2003 are used as reference predicates representative of LSI SOLUTIONS® Suture Placement Devices and the technological differences between the predicate and subject device.

Device Description

Each LSI SOLUTIONS® LS-5™ ePTFE sterile surgical suture with 2 ferrules is held in a customized tray, with a suture release feature and is intended for single patient use. The LS-5™ ePTFE Suture is designed to enable the rapid, easy and reliable loading of suture into compatible LSI SOLUTIONS® Suture Placement Devices. LS-5™ ePTFE Suture is a non-absorbable, monofilament expanded polytetrafluoroethylene (ePTFE) suture. A short length of modified surgical stainless steel tubing, called a ferrule, is attached to each end of the suture for interfacing with LSI SOLUTIONS® Suture Placement Devices. The LS-5™ ePTFE Suture also includes a detachable clear suture tube to keep the suture from tangling. The LS-5™ ePTFE Suture is undyed and contains no additives. No significant loss in tensile strength retention occurs in vivo. The LS-5™ ePTFE Suture is MR safe.

Intended Use

The LS-5™ ePTFE Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery.

The predicate device, GORE-TEX® Suture, is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery, but not for use in ophthalmic surgery, microsurgery, and neural tissue. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

According to the FDA Guidance for Industry, *Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA*, any surgery types, body sites, or patient populations where evidence demonstrates that the suture should not be used should be included in the contraindications of the labeling. The LS-5™ ePTFE Suture will include a contraindication that the subject device is not for use in ophthalmic surgery, microsurgery, and neural tissue. Therefore, the difference in indications do not impact the safety and effectiveness of the LS-5™ ePTFE Suture. Both the subject and predicate device are intended to be used in the approximation of all types of soft tissue approximation, including use in cardiovascular surgery, and are contraindicated for use in ophthalmic surgery, microsurgery, and neural tissue.

Technological Characteristics (comparison to Predicate Device)

The LS-5™ ePTFE Suture is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate device. Both the subject and predicate devices are non-absorbable, monofilament suture manufactured from ePTFE. The surgical suture of both the subject and predicate devices is undyed and contains no additives. The LS-5™ ePTFE Suture will be offered swaged on LSI's proprietary stainless steel ferrules for use with LSI's automated suturing technology. The ferrule attachments are the only technological difference between the LS-5™ ePTFE Suture and the predicate device. The ferrules are attached to both ends of the suture in the same manner as standard needle attachments and facilitate the use of the suture with the reference predicate, LSI SOLUTIONS® Suture Placement Devices. The ferrules have identical material characteristics as the ferrules used in the reference device, specifically LSI Non-Absorbable QUICK LOAD® Suture. Similar to standard needle attachments, once suturing is complete, the ferrules are removed from the suture.

The subject device is packaged and sterilized in an equivalent manner and has equivalent labeling claims to the predicate and reference predicate devices, including indications, contraindications,

warnings, cautions and precautions. The subject 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 Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA*, the LS-5™ ePTFE Suture was subject to the requirements of the United States Pharmacopeia (USP) monograph for Nonabsorbable Sutures. Performance testing includes:

- *Sutures - Tensile Strength* <881>
- Ferrule Attachment which complies with the requirements for standard needle attachments as defined in *Sutures – Needle Attachment* <871>.

The LS-5™ ePTFE Suture is offered with a surgical suture diameter comparable to the predicate device, CV-5 GORE-TEX® Suture, which is designated to approximately correlate with a surgical suture diameter of USP size 2-0. Both the LS-5™ ePTFE Suture and predicate device are manufactured from ePTFE. The internal microporous airspaces of ePTFE that result from expanding pure polytetrafluoroethylene (PTFE) produce a less dense structure that slightly exceed USP requirements for Nonabsorbable Sutures Section <861> *Sutures - Diameter*. LSI has performed testing to demonstrate the LS-5™ ePTFE Suture is comparable to CV-5 GORE-TEX® Suture for surgical suture diameter.

The LS-5™ ePTFE Suture is also similar to CV-5 GORE-TEX® Suture for tensile strength and needle attachment, which is promoted as being comparable to USP size 4-0 surgical suture. LSI has performed testing to demonstrate the LS-5™ ePTFE Suture is comparable to the predicate device for tensile strength and needle attachment and complies with USP requirements for Nonabsorbable Sutures Section <881> *Sutures - Tensile Strength* and Section <871> *Sutures – Needle Attachment* for 4-0 suture. In accordance with the FDA Guidance for Industry, *Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA*, the labeling of the LS-5™ ePTFE Suture will include a tabular comparison of its diameter and tensile

strength to the predicate device and a tabular comparison of the USP requirements for USP size 2-0, 3-0 and 4-0.

Biocompatibility evaluation for the LS-5™ ePTFE Suture was conducted in accordance with the FDA Guidance for Industry, *Use of International Standard ISO 10993-1:2009, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*," to demonstrate that the LS-5™ ePTFE Suture is biocompatible and substantially equivalent to the predicate device. The LS-5™ ePTFE Suture is classified as an implant device, contacting blood, for a permanent duration, which is the identical type and duration of patient contact as the predicate device. LSI has leveraged the following biocompatibility testing from the manufacturer of the ePTFE suture material:

- USP Systemic Toxicity Study
- USP Intracutaneous Toxicity Study
- USP Muscle Implantation Study

Additionally, LSI has conducted the following biocompatibility testing:

- Cytotoxicity
- Sensitization
- Irritation
- Rabbit Pyrogen
- Hemocompatibility

The ePTFE suture material used in the LS-5™ ePTFE Suture is proven to be remarkably inert and the same polymer that the legally marketed predicate device is made of. A combination of testing and risk assessment was completed to ensure the biocompatibility of the LS-5™ ePTFE Suture.

LSI has also performed testing to ensure that the LS-5™ ePTFE Suture is compatible with the LSI SOLUTIONS® Suture Placement Devices, Bacterial Endotoxins Testing (BET) to confirm that the subject device does not contain gram-negative endotoxins and stability testing to support the labeled 2 year shelf life.

Clinical Testing

The technological characteristics, indications for use, material, manufacturing and sterilization processes are the same as the predicate and reference predicate devices, therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Substantial Equivalence

Both the GORE-TEX® Suture and the LS-5™ ePTFE Suture are non-absorbable, monofilament ePTFE surgical suture that are indicated for the use in all types of soft tissue approximation, including use in cardiovascular surgery. The differences between the subject and predicate device introduce no new risks and have no negative impact to the safety and effectiveness of the surgical suture. The LS-5™ ePTFE Suture is substantially equivalent to the currently marketed W. L. Gore and Associates, Inc. GORE-TEX® Suture which was approved under Premarket Approval Number P820083 on December 30, 1985 and was reclassified to Class II on September 9, 1999 (reference 21 CFR Part 878, Docket No. 94P-0347).