12. Premarket Notification [510(k)] Summary

Submitted By: LSI SOLUTIONS, Inc.
7796 Victor-Mendon Road
Victor, New York 14564
Phone: (585) 869-6600
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Contact: Christopher A. Klaczyk, Regulatory Compliance Manager

Common Name: Surgical Suture

Trade Name: LSI SOLUTIONS® Suture Quick Load® Products

Proprietary Name:

1. *SEW-RIGHT*® Quick Load® with 0 Polyester
2. *SEW-RIGHT*® Quick Load® with 2-0 Polyester
3. *SEW-RIGHT*® *DUO*™ Quick Load® with 2-0 Polyester
4. *SEW-RIGHT*® Quick Load® with 2-0 Polypropylene
5. QLU, SRF-5QL™ Suture, Sterile
6. *SEW-RIGHT*® Quick Load® with 2-0 STRONGSORB™
7. *SEW-RIGHT*® Quick Load® with 2-0 MONOGLIDE™

Classification: All products are Class II per the following references:

1. No regulation specified. Nearest reference is 21 CFR 878.5000
   Nonabsorbable poly(ethylene teraphthalate) surgical suture
2. No regulation specified. Nearest reference is 21 CFR 878.5000
   Nonabsorbable poly(ethylene teraphthalate) surgical suture
3. No regulation specified. Nearest reference is 21 CFR 878.5000
   Nonabsorbable poly(ethylene teraphthalate) surgical suture
4. 21 CFR 878.5010
   Nonabsorbable polypropylene surgical suture
5. 21 CFR 878.5010
   Nonabsorbable polypropylene surgical suture
6. 21 CFR 878.4493
   Absorbable poly(glycolide/L-lactide) surgical suture
7. 21 CFR 878.4840
   Absorbable poly(dioxanone) surgical suture

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Predicate Device:

1. Deknatel™ Tevdek® II Surgical Suture (K930738)
2. Deknatel™ Tevdek® II Surgical Suture (K930738)
3. Deknatel™ Tevdek® II Surgical Suture (K930738)
4. Deknatel™ Deklene® II Surgical Suture (K930738)
5. Deknatel™ Deklene® II Surgical Suture (K930738)
6. Surgisorb Absorbable Suture (K984374)
7. Mono-Dox Synthetic Absorbable PDS Suture (K013274)

Description:

The LSI SOLUTIONS® Suture Quick Load® Products, like the predicates, are intended for the approximation of soft tissue by passing ligature through said soft tissue. The LSI SOLUTIONS® Suture Quick Load® Products have Ferrule attachments, similar to needle attachments, that facilitate the use of the suture with the LSI SOLUTIONS® *SEW-RIGHT*® family and *PLACE-RIGHT*® family of suture placement device products.

Intended Use:

For polyester and polypropylene LSI SOLUTIONS® Suture Quick Load® Products: general soft tissue approximation and/or ligation.

For polyglycolic acid (PGA) and polydioxanone (PDS) LSI SOLUTIONS® Suture Quick Load® Products: general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2003

Mr. Christopher A. Klaczyk
Regulatory Compliance Manager
LSI Solutions, Inc.
7796 Victor-Mendon Road
Victor, New York 14564

Re: K031443
Trade/Device Name: Suture Quick Load® Products
Regulation Number: 21 CFR 878.4840
21 CFR 878.4493
21 CFR 878.5000
21 CFR 878.5010
Regulation Name: Suture, surgical, absorbable, polydioxanone
Absorbable poly(glycolide/L-lactide) surgical suture
Nonabsorbable poly(ethylene terephthalate) surgical suture
Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: NEW, GAM, GAS, GAW
Dated: May 2, 2003
Received: May 8, 2003

Dear Mr. Klaczyk:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031443

7. Statement of Indications For Use

510(k) Number (if known): K031443

Device Name: LSI SOLUTIONS® Suture Quick Load® Products

Indications For Use For Polyester Quick Load® Products:

The *SEW-RIGHT*® Quick Load® Unit with PTFE coated, braided polyester surgical suture is indicated for use in general soft tissue approximation and/or ligation.

Indications For Use For Polypropylene Quick Load® Products:

The *SEW-RIGHT*® Quick Load® Unit with monofilament polypropylene surgical suture is indicated for use in general soft tissue approximation and/or ligation.

Indications For Use For Polyglycolic Acid (PGA) Quick Load® Products:

The *SEW-RIGHT*® Quick Load® Unit with STRONGSORB™ synthetic absorbable surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Indications For Use For Polydioxanone (PDS) Quick Load® Products:

The *SEW-RIGHT*® Quick Load® Unit with Monoglide™ synthetic absorbable surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K031443