K981531

JUL 13 1998

Premarket Notification [510(k)] Summary

LSI SOLUTIONS
2144 Brighton-Henrietta Town Line Road
Rochester, New York 14623
Phone: 716-427-7979
Fax: 716-427-7482
Contact: Jude. S. Sauer, M.D., President and CEO or
Nicholas Reitter IV, Director of Regulatory Compliance

April 28, 1998

Common Name: Needle Guide

Trade Name: The trademark name has not yet been determined.

Classification Name: Manual Surgical Instrument for General Use (per 21 CFR, §878.4800) and an accessory to an endoscope (per 21 CFR §876.1500).

Predicate Device: AUTO SUTURE* Suture Closure** device and accessories (K954853)

Description: The LSI Suture Placement device and accessories intended for the approximation of surgical wounds by passing ligature through soft tissue.

Intended Use: The LSI Suture Placement device and accessories are intended for use in the approximation of soft tissue.

Comparison

Summary of how the device and accessories of this application compare to the predicate device. Both the subject device and accessories and the predicate device and accessories use the same technology.

Function	The LSI SOLUTIONS Suture Placement device and accessories deliver suture materials to the site of application.	The AUTO SUTURE* Suture Closure** device and accessories deliver suture materials to the site of application.
Indication	The LSI SOLUTIONS Suture Placement device and accessories approximate soft tissue.	The AUTO SUTURE* Suture Closure** device and accessories approximate soft tissue.
Materials	The LSI SOLUTIONS Suture Placement device and accessories use biocompatible materials.	The AUTO SUTURE* Suture Closure** device and accessories use biocompatible materials.
Sterilization	The LSI SOLUTIONS Suture Placement device and accessories are sterilized with ethylene oxide (EtO) such that a minimum lethality of 10^{-6} (a MSI of 6) is achieved.	The AUTO SUTURE* Suture Closure** device and accessories are sterilized with ethylene oxide (EtO) such that a minimum lethality of 10^{-6} (a MSI of 6) is achieved.
Packaging	The LSI SOLUTIONS Suture Placement device and accessories are disposable devices that are packaged in a thermoformed blister with a TYVEK™ cover.	The AUTO SUTURE* Suture Closure** device and accessories are disposable devices that are packaged in a thermoformed blister with a TYVEK™ cover.

Summary

The LSI SOLUTIONS Suture Placement device and accessories are substantially equivalent to the AUTO SUTURE* Suture Closure** device and accessories (K954853). Both devices have the same design, function, and indicated use.

Description

The LSI Suture Placement device and accessories are intended for the approximation of soft tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1998

Jude S. Sauer, M.D.
President
LSI Solutions
2144 Brighton-Henrietta Town Line Road
Rochester, New York 14623

Re: K981531
Trade Name: Suture Placement Device and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 28, 1998
Received: April 29, 1998

Dear Dr. Sauer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) NUMBER (IF KNOWN): K981531

DEVICE NAME: SUTURE PLACEMENT DEVICE AND ACCESSORIES

INDICATIONS FOR USE:

The LSI Suture Placement device and accessories are intended for use in the approximation of soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ___ (Optional Format 1-2-96)

[redacted]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981531