

K090385

SECTION 4 - 510(K) SUMMARY

MAY - 6 2009

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) number: _____

Date Prepared:

February 2009

Applicant Information:

SentreHEART
2468 Embarcadero Way
Palo Alto, CA 94303

Contact Person:

Linda Guthrie, Manager Regulatory Affairs
Phone Number: (650) 354-1200 x105
Fax Number: (650) 354-1204

Device Information:

Trade Name: LARIAT II Suture Delivery Device
Classification: Class II per 21CFR 878.5000
Regulation Name: Suture, Nonabsorbable, Synthetic
Product Code: GAT

Physical Description:

The LARIAT II Suture Delivery Device is a one-piece, single-use suture delivery and deployment device with a pre-tied size 0 polyester suture loop that is pre-loaded on the device. A lumen within the LARIAT II is designed for aspiration, flushing during the delivery, capture or release of the LARIAT II Suture.

The LARIAT II is packaged with a guide cannula and a dilator which may be used for guidance and placement of the LARIAT II, and a surgical blade which is used for cutting excess suture.

The suture is itself a cleared medical device as a part of Pre-Market Notification K021019.

Intended Use:

The LARIAT II Suture Delivery Device facilitates suture placement and knot tying for use in surgical applications where soft tissue are being approximated and/or ligated with a pre-tied polyester suture.

SECTION 4 - 510(k) SUMMARYPredicate Devices:

Lariat Loop Applicator, SentreHEART (K060721)

Endosuture System, Ethicon Endo-Surgery (K963329)

Saph-Loop Ligating Loop, Genzyme (K022410)

Surgietie Ligating Loop US Surgical (K905379)

Safety and Performance:*Performance*

Functional testing was conducted to support the claim of substantial equivalence and to demonstrate the LARIAT II is safe and effective for its intended use.

Biocompatibility

The materials used in the LARIAT II are commonly used materials in other medical devices. Results of testing demonstrate the LARIAT II is biocompatible.

Summary:

Based on the intended use, product testing, and information provided in this notification, the subject device has been shown to be safe and effective for its intended use and substantially equivalent to the predicate devices.



MAY - 6 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SentreHeart, Inc.
% Ms. Linda Guthrie
Manager, Regulatory Affairs
2468 Embarcadero Way
Palo Alto, California 94303

Re: K090385

Trade/Device Name: LARIAT II Suture Deliver Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, HCF
Dated: February 12, 2009
Received: February 17, 2009

Dear Ms. Guthrie:

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 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.

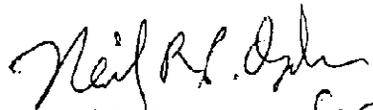
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

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(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson *for*
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090385

Device Name: LARIAT II Suture Delivery Device

Indications for Use:

The LARIAT II Suture Delivery Device facilitates suture placement and knot tying for use in surgical applications where soft tissue are being approximated and/or ligated with a pre-tied polyester suture.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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