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

November 25, 2015

SentreHEART, Inc.
Kit Cariquitan
V.P. of Clinical and Regulatory Affairs
300 Saginaw Drive
Redwood City, California 94063

Re: K153096
Trade/Device Name: LARIAT RS Suture Delivery Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, HCF
Dated: October 16, 2015
Received: October 26, 2015

Dear Kit Cariquitan:

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" (21CFR 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)*
K153096

Device Name

LARIAT® RS Suture Delivery Device

Indications for Use *(Describe)*

The LARIAT® RS 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

GENERAL INFORMATION

Submitter:

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Phone: 650-241-6038
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Contact Person:

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Phone: 650-241-6038
Fax: 650-241-5985
Email: kcariquitan@sentreheart.com

Date Prepared: October 16, 2015

Classification:

Class II, 21 CFR§870.5000

Product Code:

GAT (Suture, Nonabsorbable, Synthetic, Polyethylene)
HCF (Instrument, Ligature Passing And Knot Tying)

Trade Name:

LARIAT® RS Suture Delivery Device

Generic/Common Name:

Nonabsorbable (ethylene terephthalate) surgical suture
Instrument, Ligature Passing And Knot Tying

Predicate Device:

LARIAT III Suture Delivery Device, SentreHEART (K142241)

This predicate has not been subject to a design-related recall.

510(k) SUMMARY (CONT.)

No reference devices were used in this submission.

Indications for Use:

The LARIAT® RS 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.

The Indications for Use statement for the LARIAT RS Suture Delivery Device is identical to the predicate device.

Product Description:

The LARIAT® RS 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 a retractable Delivery Snare on the distal end of the device. The pre-tied suture loop is held onto the Delivery Snare and allows for multiple opening and closings of the suture loop without release. Upon tightening of the suture loop, the suture is released from the Delivery Snare. An accessory lumen within the LARIAT RS device is designed for aspiration, flushing or to accommodate a guide wire of up to 0.035" diameter. The LARIAT RS device offers the additional feature of allowing the user to release the Delivery Snare from the tissue during device removal from the target location following suture deployment. The LARIAT RS device is compatible with access site diameters of 4.3mm and larger. The suture is itself a cleared medical device as a part of K021019.

Substantial Equivalence:

This Special 510(k) is for the LARIAT RS device, which is a modified version of the cleared LARIAT III device (K142241), which is currently marketed as the LARIAT+ device. The LARIAT III device's catheter handle has been modified to allow the user to release the Delivery Snare following suture deployment. In order to release the Delivery Snare, the catheter handle now has a Snare Release Actuator, which allows the fixed end of the Delivery Snare to be released from the tip. The Delivery Snare size remains unchanged from the predicate device at 45mm. The LARIAT RS device and the cleared and commercially available LARIAT III device are both single-use suture delivery and deployment devices. The minor design modifications outlined in this Special 510(k) do not (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Any differences between the devices do not raise any new issues of safety or effectiveness. Thus, the LARIAT RS device is substantially equivalent to the predicate device.

Testing in Support of Substantial Equivalence Determination:

All necessary bench testing was conducted on the LARIAT RS device to support a determination of substantial equivalence to the predicate device.

SECTION 6
510(k) SUMMARY (CONT.)

The bench testing included the following:

• Visual and Dimensional Verification	• Snare Wire Joint Strength Testing
• Snare Loop Actuation and Force Testing	• Shaft to Handle Joint Strength Testing
• Ability to Perfuse and Aspirate Testing	• Catheter Tip to Shaft Joint Strength Testing
• Suture Preparation and Deployment Testing	• Snare Anchor Joint Strength Testing
• Snare Loop Lock Testing	• Hypotube to Shaft Joint Strength Testing
• Suture Recoil Testing	• Suture Knot Strength Testing
• Suture Tensile Strength Testing	• Suture/Suture Fob Joint Strength Testing

The above testing confirms that the LARIAT RS device performs according to the stated intended use.

Summary:

The LARIAT RS device is substantially equivalent to the predicate device.