510(k) Summary

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.
Date Prepared: March 10, 2006

510(k) number: _____

JUN - 2 2006

Applicant Information:
SentreHeart
2468 Embarcadero Way
Palo Alto, CA 94303

Contact Person
Russell Seiber
Phone Number: (650) 354-1200
Fax Number: (650) 354-1204

Device Information:

Trade Name:	LARIAT Loop Applicator
Classification:	Class II
Classification Name:	Suture, Non-absorbable, Synthetic

Physical Description:
The LARIAT Loop Applicator is a one piece, single-use suture delivery and deployment device with a pre-tied polyester suture loop that is pre-loaded on the device. A central lumen within the LARIAT Loop Applicator is designed for aspiration and stabilization of tissue during the delivery of the LARIAT Suture Loop.

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

Intended Use:
The LARIAT Loop Applicator 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.

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Ethicon Endosuture System (K963329), the Genzyme Saph-Loop Ligating Loop (K022410), and the HysteRx Liga-Loop Suture Applicator (K993695).

Test Results:

Performance
Results of in-vitro testing demonstrate that the LARIAT Loop Applicator is safe and effective for its intended use.

Biocompatibility
Results of testing demonstrate that the materials used in the LARIAT Loop Applicator are biocompatible. The materials are used in the identified predicates and are also commonly used in other medical devices.

Summary:
Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

SentreHeart™
% Mr. Robert Chin
Regulatory Consultant
2468 Embarcadero Way
Palo Alto, California 94303

Re: K060721
Trade/Device Name: LARIAT Loop Applicator
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulation Class: II
Product Code: GAT
Dated: May 24, 2006
Received: May 25, 2006

Dear Mr. Chin:

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.

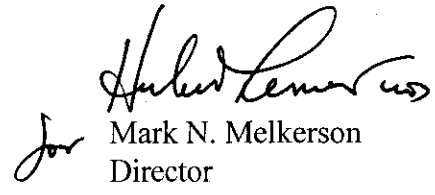
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060721

Device Name: LARIAT Loop Applicator

Indications for Use:

The LARIAT Loop Applicator 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 √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page __ of __

510(k) Number K060721