DEC 2 7 2005

K053482

Page 1 of 2

510(k) SUMMARY

Sutura, Inc.'s SuperStitch GW

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sutura, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Phone: (714) 437-9801
Facsimile: (714) 437-9806

Contact Person: Anthony Nobles
Date Prepared: December 14, 2005

Alternate Contact:

Gerard J. Prud'homme
Hogan & Hartson L.L.P.
555 Thirteenth St. NW
Washington D.C., 20004
Phone: (202) 637-5600

Name of Device and Name/Address of Sponsor

SuperStitch GW

Sutura, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Common or Usual Name

SuperStitch Guidewire Vascular Suture Delivery Device

Classification Name

Suture, Nonabsorbable, Synthetic, Polypropolene

Predicate Devices

Sutura's SuperStitchVascular Suturing Device

Intended Use

The SuperStitch GW is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SuperStitch GW is not intended for blind vascular closure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Sutura, Inc.
% Mr. Gerard J. Prud'Homme, Esquire
Hogan & Hartson L.L.P.
555 13th Street, NW
Washington, DC 20004

Re: K053482
Trade/Device Name: Superstich GW
Models 06-15-04-GW; 08-15-04-GW
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: December 14, 2005
Received: December 14, 2005

Dear Mr. Prud'Homme:

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/industry/support/index.html.

Sincerely yours,

Barbara Zuchwo
for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K053482

Device Name: SuperStitch Guide-wire Vascular Suture Delivery Device

Indications for Use:

The SuperStitch GW is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SuperStitch GW is not intended for blind vascular closure.

Prescription Use __X___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mulvey

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

510(k) Number K053482