SEP 2 5 2001

XI. 510(k) Summary

A. Sponsor/Submitter:

Sutura, Inc.
17080 Newhope Street
Fountain Valley, CA 92708
Tel: 714.437.9801
Fax: 714.437.9806

B. Contact Person:

James Bonds
Vice President, QA/RA

C. Date of Submission: August 24, 2001

D. Trade Name: SuperStitch® Vascular Suture Delivery Device

E. Common Name: Suture Delivery Device

F. Classification: Class II

G. Classification Name: Suture, Nonabsorbable, Synthetic, Polypropylene

H. Product Code: GAW, GAB

I. Predicate Device: Sutura SuperStitch®, K994087

J. Intended Use:

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

K. Device Description:

The SuperStitch® Vascular Suture Delivery Device is a hand-held and operated device designed for use with or without an access device (e.g. trocar, sheath, or cannula), depending on the endoscopic technique, for use during minimally invasive surgical procedures, or for application directly to a vessel or wound site in an open setting. The SuperStitch® applies one nonabsorbable monofilament suture. After deployment of the device, the physician completes the closure by tying the appropriate surgical knots. Optional accessories for use with the SuperStitch® include the KnotPusher™

for advancing the knot to the wound site and the Kwiknot™ knot tying device

The principal differences between the modified SuperStitch® and the cleared SuperStitch® are: (1) changes made within the operating mechanism to improve manufacturability; (2) the addition of longer lengths to accommodate longer (i.e., 25cm) sheaths; (3) change in package to a single sterile barrier; (4) the inclusion of a modified KnotPusher™ accessory that is packaged with the SuperStitch® (5) a change in one of the cannula materials; and (6) the addition of a smaller (6 French) size for compatibility with 6 French procedural sheaths.

The Sutura SuperStitch® is a prescription device, restricted to use by or on the order of physicians.

The Sutura SuperStitch® is sterilized by ethylene oxide and is non-pyrogenic in an unopened undamaged package, for single use only.

L. Summary of Substantial Equivalence:

Sutura, Inc. has submitted information on the design, indications, materials, and principle of operation to establish that the modified SuperStitch® Vascular Suture Delivery Device is substantially equivalent to the predicate unmodified SuperStitch® Vascular Suturing Device.

The Sutura SuperStitch® has the same intended use as the predicate device. The differences in the technological characteristics and size of the modified SuperStitch® have been evaluated through appropriate design control procedures. These methods assessed the new characteristics with regard to functionality and reliability under simulated and actual conditions of use. Results of scientific testing have ensured that the materials are biocompatible and physical properties are appropriate for the intended use.

In conclusion, the Sutura SuperStitch® Vascular Suture Delivery Device has been shown to be substantially equivalent to the Class II predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2001

Mr. James Bonds
Vice President, Quality Assurance
and Regulatory Affairs
Sutura, Incorporated
17080 Newhope Street
Fountain Valley, California 92708

Re: K012865
Trade/Device Name: SuperStitch® Vascular Suturing Device
Regulation Number: 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: August 24, 2001
Received: August 27, 2001

Dear Mr. Bonds:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Celia M. Witten, Ph.D., M.D.
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: K012865

Device Name: SuperStitch® vascular suturing device

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milleson

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

510(k) Number K012865

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)