DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sutura™, Inc.
Mr. Dave Barry
Vice President, Regulatory Affairs
and Quality Assurance
17080 Newhope Street
Fountain Valle,y CA 92708

JUL 27 2015

Re: K994087
Trade/Device Name: SuperStitch® Vascular Suturing Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, OCW, GAW
Dated (Date on orig SE ltr): December 1, 1999
Received (Date on orig SE ltr): December 3, 1999

Dear Mr. Barry,

This letter corrects our substantially equivalent letter of March 1, 2000.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K994087

INDICATIONS FOR USE STATEMENT

Sutura™, Inc.

SuperStitch®

510(k) Number: K994087

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 Drug Evaluation (ODE)

NKO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994087

Prescription Use YES
(Per 21 CFR 801.109)

MAR - 1 2000

K994087

SUMMARY OF SAFETY AND EFFECTIVENESS

Sutura™, Inc.

SuperStitch®

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.

Company: Sutura™, Inc.
17080 Newhope Street
Fountain Valley, CA 92708
Phone: (714) 437-9801
Fax: (714) 437-9806

Company Representative: David B. Barry
Vice President, RA/QA

Date 510(k) Prepared: December 1, 1999

Device Name: SuperStitch® vascular suturing device

Classification Name: Needle, Suturing, Disposable (21 CFR §878.4800)

Product Code: GCJ

Classification: Class II

Devices to which Equivalence is Claimed

Automatic suturing devices are made by various manufacturers. The technological characteristics of the SuperStitch® and accessory Knot Pusher are substantially equivalent to the following devices:

Vascular Stitcher (K963965), CardioThoracic Systems, Inc.
AutoSuture™ Endoscopic Suturing Device (K934738), U.S. Surgical Corporation
AutoSuture Endoscopic Knot Pusher™ (K925149), U.S. Surgical Corporation

Indication 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.

Device Description:

The SuperStitch® device is designed for use with or without an access device (e.g., trocar, sheath, or cannula) depending on the endoscopic technique, for use during

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minimally invasive surgical procedures, or for application directly to a vessel or wound site in an open setting. SuperStitch® applies one nonabsorbable sterile surgical suture.

The knot pusher is comprised of two components: a snare to capture one strand of the suture and a tubular body that is used to advance the tied knot to the surface of the tissue.