K030227 page 1/2

MAR 17 2003

SuturTek
51 Middlesex Street
North Chelmsford
Massachusetts 01863
(978)-251-8088

510K Summary of Safety and Effectiveness
January 14, 2003
SuturTek FASTCLOSE™ Suturing Device

1. Sponsor Name

SuturTek
51 Middlesex Street
North Chelmsford
Massachusetts 01863
(978)-251-8088
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: FASTCLOSE™
Common/Usual Name: Suture
Panel: General and Plastic Surgery
Class II 878.4830, 878.4800
GAL, GAB, HCF

3. Identification of Legally Marketed Device

The modified SuturTek FASTCLOSE™ Suturing Device is substantially equivalent to the SuturTek FASTCLOSE™ Suturing Device K011105.

4. Device Description

The FASTCLOSE Device has four major components: 1) a reusable instrument, 2) a single-use, disposable cartridge, 3) a single-use, disposable needle, and 4) sutures.

The cartridge containing the needle (with suture attached) is loaded onto the distal end of the device. The needle is engaged by the device's internal drive mechanism and driven through the tissue to be sutured. The suture is thus passed completely through the wound. Once the suture is in place, the device is withdrawn from the incision leaving the suture strand looped through the tissue. The two ends of the suture are then tied together in the usual manner.

5. Intended Use

The SuturTek Incorporated FASTCLOSE Suturing Device is intended for soft tissue approximation and/or ligation in general surgical procedures.

The use of this device with absorbable sutures is not indicated for use in cardiovascular and neurological procedures.

It is designed to aid in the prevention of accidental suture needle stick injuries.

6. Comparison of Technological Characteristics

The proposed SuturTek FASTCLOSE™ Suturing Device and the currently marketed device:

Have the same intended use

Both are intended for soft tissue approximation and/or ligation in general surgical procedures.

Use the same fundamental scientific technology

- Manual instrument passes a needle through tissue to place sutures
- Have the same components
  reusable instrument
  single-use, disposable cartridge
  single-use, disposable needle
  sutures

The differences between the proposed SuturTek FASTCLOSE™ Suturing Device, and the current SuturTek FASTCLOSE™ Suturing Device, K011105 are:

- Added Sharps Injury Prevention Feature Claims

7. Performance Testing

Tests applicable to the type of safety device and safety features of the FASTCLOSE Device per the FDA Guidance on the Content of Premarket Notification Submissions for Medical Devices with Sharps Injury Prevention Features" (March 1995) were:

Simulated Use Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

SuturTek Incorporated
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K030227
Trade/Device Name: SuturTek FASTCLOSE™ Suturing Device
Regulation Number: 21 CFR 878.4830
Regulation Name: Absorbable surgical gut suture
Regulatory Class: II
Product Code: GAL
Dated: January 14, 2003
Received: January 22, 2003

Dear Ms. Iampietro:

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 (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) you may obtain. 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,

Miriam C. Provost

for 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

510(k) Number (if known): K030227

Device Name: SuturTek FASTCLOSE™ Suturing Device

Indications For Use:

The SuturTek FASTCLOSE Suturing Device is intended for soft tissue approximation and/or ligation in general surgical procedures.

The use of this device with absorbable sutures is not indicated for use in cardiovascular and neurological procedures.

It is designed to aid in the prevention of suture needle stick injuries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030227

000063