510(k) Summary of Safety and Effectiveness
SuturTek FASTCLOSE Sternum Closure Device
August 8, 2003

1. Sponsor Name

Sponsor/Manufacturer:

SuturTek Incorporated
51 Middlesex Street
North Chelmsford, Massachusetts 01863
Telephone: 978-251-8088
FAX: 978-251-8585

2. Device Name

Proprietary Name: FASTCLOSE™ Sternum Closure Device

Common/Usual Name: Suture, Nonabsorbable, Steel, Monofilament And Multifilament

Panel: General Surgery
Product Code: GAQ
878.4495 - Suture, Nonabsorbable, Steel, Monofilament And Multifilament

3. Identification of Predicate or Legally Marketed Device

SuturTek FASTCLOSE Fascia Closure Device K011105
SuturTek FASTCLOSE Fascia Closure Device K030227
Aesculap Steelex Sternum Set K023411

4. Device Description

The FASTCLOSE Sternum Closure 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 sternum 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 Once the suture is in place, the device is withdrawn from the incision leaving the suture strand looped through the sternum. Additional interrupted stitches are place in the same manner and then the two ends of each suture are tied together in the usual fashion.

5. Intended Use

The FASTCLOSE Sternum Closure Device is intended for use during thoracic surgery to hold and close the sternum after a sternotomy.

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

6. Comparison of Technological Characteristics

The FASTCLOSE Sternum Closure Device is substantially equivalent in its intended use and/or function to the following predicate devices:

SuturTek FASTCLOSE Fascia Closure Device K011105
SuturTek FASTCLOSE Fascia Closure Device K030227
Aesculap Steelex Sternum Set K023411

The operating principle, materials, intended use and design of construction of the FASTCLOSE Sternum Closure Device is the same as that of the predicate devices: a manual instrument is used to pass stainless steel needles through sternum for fixation with stainless steel sutures.

7 Performance Testing

Bench testing was performed to demonstrate that the FASTCLOSE Sternum Closure Device would perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

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

Re: K032468
Trade/Device Name: FASTCLOSE Sternum Closure Device
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: August 8, 2003
Received: August 19, 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. 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,

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

K032468

510(k) Number (if known): _____

Device Name: FASTCLOSE Sternum Closure Device

Indications For Use:

The FASTCLOSE Sternum Closure Device is intended for use during thoracic surgery to hold and close the sternum after a sternotomy. It is designed to aid in the prevention of suture needlestick 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 K032468