K063603 1/2

# 510(k) Summary of Safety and Effectiveness
# SuturTek Surgical Steel Suture
# December 1, 2006

FEB 7 2007

1. Sponsor Name

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

2. Contact person:

A. Arthur Rankis
508 847-5961

3. Device Name

Proprietary Name: SuturTek Surgical Steel Suture

Common/Usual Name: Surgical Suture, Nonabsorbable, Stainless Steel.

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

4. Identification of Predicate or Legally Marketed Devices

Aesculap: Steelex Sternum Set; K023411
CP Medical: Surgical Steel Monofilament Stainless Steel; K030351

5. Device Description

The SuturTek Surgical Steel Suture is for use during thoracic surgery to hold and close the sternum after a sternotomy (i.e. for use in sternal closure).

The SuturTek Surgical Steel Suture is a sterile, single-use, non absorbable, stainless steel monofilament suture. It is designed to remain inside the patient. It may or may not be attached to a stainless steel needle. The needle and any unused portions of suture are disposables.

6. Intended Use

The SuturTek Surgical Steel Suture is intended for use in sternal closure.

7. Comparison of Technological Characteristics

The SuturTek Surgical Steel Suture is substantially equivalent in its intended use and/or function to the following predicate devices:

Aesculap: Steelex Sternum Set; K023411
CP Medical: Surgical Steel Monofilament Stainless Steel; K030351

The operating principle, materials, intended use and design of construction of the SuturTek Surgical Steel Suture 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.

8. Performance Testing

Bench testing was performed to demonstrate that the SuturTek Surgical Steel Suture would perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SuturTek Incorporated
% A. A. Rankis & Associates
Mr. A. Arthur Rankis
President
6 Brookside Circle
Acton, Massachusetts 01720

FEB 7 2007

Re: K063603
Trade/Device Name: SuturTek Surgical Steel Suture
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: December 1, 2006
Received: December 5, 2006

Dear Mr. Rankis:

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.

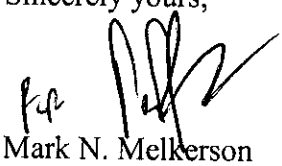
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K063603

Device Name: SuturTek Surgical Steel Suture

Indications For Use:

The SuturTek Surgical Steel Suture is intended for use in sternal closure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063603