K023411

VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS [Accordance with SMDA of 1990]

Steelex Sternum Set

October 10, 2002

DEC 19 2002

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Georg Keller 800-258-1946 x 5073 (phone) 610-791-6882 (fax)

TRADE NAME:	Steelex Sternum Set
COMMON NAME:	Stainless Steel Suture
DEVICE CLASS:	Class II
PRODUCT CODE:	79GAQ
CLASSIFICATION:	878.4495 – Suture, Nonabsorbable, Steel, Monofilament And Multifilament
REVIEW PANEL:	General and Plastic Surgery

INDICATIONS FOR USE

The Steelex Sternum Set is indicated in abdominal surgery, for orthopedic procedures (tendon operations and cerclages), hernia surgery and sternal closure. It is designed to remain inside the patient.

DEVICE DESCRIPTION

The Steelex Sternum Set consists of a corrosion-resistant steel monofilament suture with a specially designed HRS needle for the sternum closure. The set consists of a combination of 2 or 4 steel wire monofilaments armed with a tapercut round bodied needle fixed or rotating. The wire for Steelex Sternum Set is made of stainless steel 316L (ASTM-F138) and the needle is made of stainless steel 302, 420 or 420F (ASTM-F899). The needle sizes for Steelex Sternum Set are available in the USP sizes 3, 4, 5, 6 and 7.

PURPOSE FOR SUBMISSION

This submission seeks marketing clearance for Aesculap's Steelex Sternum Set.

PERFORMANCE DATA

All required testing per USP for Steelex Sternum Set were completed Biomechanical testing results demonstrate the Steelex Sternum Set is substantially equivalent to other suture systems currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Steelex Sternum Set is substantially equivalent to:

- Ethicon, Inc. Ethi-Pack Surgical Stainless Steel Suture (K931271)
- Stony Brook Surgical Innovations Sterna-Wire (K013059)
- CardioThoracic Systems, Inc. Acier Sutures (K991073)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2002

Mr. Georg Keller
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K023411
Steelex Sternum Set
Regulation Number: 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: October 10, 2002
Received: October 11, 2002

Dear Mr. Keller:

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,

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

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K023411

Device Name: **Steelex Sternum Set**

Indication for Use:

The Steelex Sternum Set is indicated in abdominal surgery, for orthopedic procedures (tendon operations and cerclages), hernia surgery and sternal closure. It is designed to remain inside the patient.

(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

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