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IV. Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number: TBD

Applicant Information:

Date Prepared:	March 10, 2003
Name:	Advanced Surgical Products
Address:	681 Manzanita Ave Sunnyvale, CA. 94085
Contact Person:	Jeffrey S. Jones
Phone Number:	650-207-6987
Facsimile Number:	408-734-5316

Device Information:

Classification:	Class II
Trade Name:	Advanced Surgical Products, Inc. *"Fast Throw"* Suture
Common name:	STAINLESS STEEL SURGICAL SUTURE

Predicate Device:

The Advanced Surgical Products *"Fast Throw"* Stainless Steel Surgical Suture is substantially equivalent in intended use and method of operation to the following predicate devices:

Name:	LOOK Inc. 316L STAINLESS STEEL SURGICAL SUTURE
Manufacture:	LOOK, Inc.
510(k) #:	K933686
Name:	ETHI-PACK SURGICAL STAINLESS STEEL SUTURE
Manufacture:	ETHICON, Inc.
510(k) #:	K931271
Name:	STAINLESS STEEL SUTURE
Manufacture:	SURGIMETRICS INTERNATIONAL, LTD.
510(k) #:	K931915

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Name: CLIP, IMPLANTABLE
Manufacture: UNITED STATES SURGICAL
510(K) #: K970793

Device Description:

The Advanced Surgical Products *"Fast Throw"* Stainless Steel Surgical Suture is a sterile single use knot-less suture that is primarily designed for skin wound closure The device incorporates barbs along the length of the suture and works in conjunction with a T-shaped backstop incorporated at the proximal end of the device. As the suture is passed through the wound, the wound is cinched up to the T-shaped backstop.

Intended Use:

The *"Fast Throw"* Stainless Steel Surgical Suture is indicated for use in superficial skin closure.

Comparison to Predicate Devices:

The *"Fast Throw"* Stainless Steel Surgical Suture is substantially equivalent in intended use and method of operation to 316L monofilament Stainless Steel sutures and Implantable Clips currently in use.

Pre-Clinical Data:

Per USP Standards, needle attachment pull strength was performed as well as tensile testing on sterilized sutures.
In Vivo testing was performed with sterilized, packaged sutures in a controlled environment.

Summary:

Based on the product technical information, intended use, performance and biocompatibility information provided in this pre-market notification, Advanced Surgical Products, Inc. *"Fast Throw"* Stainless Steel Surgical Suture has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Mr. Jeffrey S. Jones
President
Advanced Surgical Products
681 Manzanita Avenue
Sunnyvale, California 94085

Re: K030926
Trade/Device Name: "Fast Throw" Stainless Steel Surgical Suture
Regulation Number: 21 CFR 878.4300, 878.4495
Regulation Name: Implantable clip, Stainless steel suture
Regulatory Class: II
Product Code: FZP, GAQ
Dated: May 22, 2003
Received: May 27, 2003

Dear Mr. Jones:

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

K030926

II. Indications for Use Form

510(k) number (if known):

Device Name:

Advanced Surgical Products, Inc. *"Fast Throw"* Stainless Steel Surgical Suture

Indications for Use:

The *"Fast Throw"* Stainless Steel Surgical Suture is indicated for use in superficial skin closure.

Miriam C. Provost

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

510(k) Number K030926