VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted By

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Contact: Victoria Mackinnon, Director, Regulatory Affairs & Quality Assurance
Date Prepared: January 7, 1999

B. Device Name

Trade or Proprietary Name:	*Synthofil*® Nonabsorbable PET Surgical Suture
Common or Usual Name:	Nonabsorbable Polyester Surgical Suture
Classification Name:	Nonabsorbable Poly(Ethylene terephthalate) Surgical Suture

C. Predicate Devices

- Ethibond® Nonabsorbable Polyester Surgical Suture (Ethicon, Inc.)
- Ti-Cron® Nonabsorbable Polyester Surgical Suture (Davis & Geck)
- SURGIDAC® Nonabsorbable PET Surgical Suture (U. S. Surgical Corp.)

The subject device is substantially equivalent to predicate devices listed above.

D. Device Description

The subject device is a nonabsorbable, flexible, braided multifilament suture thread which is supplied sterile. It is composed of the long-chain, linear polymer Poly(Ethylene terephthalate), and is indicated for general soft tissue approximation and/or ligation. It will be offered undyed, and dyed with the FDA listed colorant D&C Green No. 6 in accordance with Title 21 CFR, §74.3206. It will be offered uncoated, or coated with a proprietary copolymer to enhance handling characteristics. It will be available with and without standard needles attached.

E. Intended Use

Synthofil® Nonabsorbable PET Surgical Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

F. Comparison to Predicate Devices

The subject *Synthofil*® Nonabsorbable PET Surgical Suture is composed of the same material as are the predicate devices, that being the long-chain, linear polymer Poly(Ethylene terephthalate), or PET. Further, the subject device is offered undyed, and dyed with the same colorant as are the predicate devices, that being D&C Green No. 6 at a concentration of ≤0.75% by suture weight in accordance with Title 21 CFR, §74.3206. In addition, the suture is offered both uncoated, or treated with a biocompatible synthetic polymer coating to enhance its handling properties.

The subject device has the same design as do the predicate devices, being a sterile, flexible, braided multifilament thread which is offered in a variety of lengths and a range of diameters conforming with the requirements of U.S. Pharmacopeia (U.S.P.) XXIII, and which is offered with or without one of a selection of standard needles attached. Further, as is the case with the predicate devices, the subject device conforms in all respects to the requirements of the

Official Monograph for Nonabsorbable Surgical Suture in U.S.P. XXIII, including <861> *Sutures -- Diameter*, <871> *Sutures -- Needle Attachment*, and <881> *Tensile Strength.*

Physical properties of the subject device are substantially equivalent to those of the predicate devices, including fiber diameter, knot pull tensile strength, straight pull tensile strength, flexibility, elongation, knot security, and needle attachment strength.

The subject device is manufactured in the same manner as the predicate devices, being produced from PET polymer via melt-spin, drawing and braiding operations considered standard in the fiber industry. As such, the suture fiber from which the subject device is made has essentially the same physical and chemical properties, and hence, biosafety profile and *in vivo* performance characteristics, as do the predicate devices.

The subject device is packaged and sterilized in the same or equivalent manner, and has the same labeling claims, as do the predicate devices.

G. Summary of Non-Clinical Tests

Non-Clinical testing conducted on the subject device to demonstrate its substantial equivalence to predicate devices included chemical assays for identity and purity, physical testing for all parameters identified above and to prove conformance to the requirements of U.S.P., *in vitro* and *in vivo* biosafety studies, and one (1) year implant studies in animals to demonstrate retention of tensile strength.

H. Summary of Clinical Tests

(Not applicable)

I. Conclusions of Non-Clinical and Clinical Tests

The results of all testing demonstrated the substantial equivalence, if not superiority, of the subject device to one or more predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1999

Aesculap
C/o Mr. Steve Reitzler
Vice President, Regulatory Affairs
Advanced Bioresearch Associates
One America Plaza
600 West Broadway Suite 900
San Diego, California 92101-3302

Re: K990088
Trade Name: Synthofil® Nonabsorbable Poly(Ethylene terephthalate) [PET] Surgical Suture
Regulatory Class: II
Product Code: GAT
Dated: January 7, 1999
Received: January 11, 1999

Dear Mr. Reitzler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Synthofil® Nonabsorbable Poly(Ethylene terephthalate) [PET] Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than high molecular weight fibers composed of long chain linear polyester having recurrent aromatic rings as an integral component. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Synthofil® Nonabsorbable Poly(Ethylene terephthalate) [PET] Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

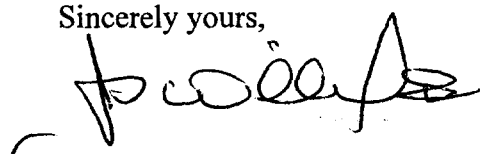
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, The Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control Provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K990088

Device Name: *Synthofil*® Nonabsorbable PET Surgical Suture

Indications for Use:

Synthofil® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990088

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