MAY 4 1998

## 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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Aesculap®
1000 Gateway Boulevard
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Telephone: (650) 876-7000
Contact: Victoria MacKinnon, Manager, Regulatory Affairs
Date Prepared: February 11, 1998

### B. Device Name

| | |
|---|---|
| Trade or Proprietary Name: | *Premilene* Polypropylene Surgical Suture |
| Common or Usual Name: | Nonabsorbable Polypropylene Surgical Suture |
| Classification Name: | Nonabsorbable Polypropylene Surgical Suture |

### C. Predicate Devices

- Prolene® Nonabsorbable Polypropylene Surgical Suture (Ethicon, Inc.)
- Surgilene® Nonabsorbable Polypropylene Surgical Suture (Davis & Geck)
- Sharpoint Polypropylene Surgical Suture (Sharpoint)

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

## D. Device Description

The subject device is a nonabsorbable, flexible monofilament suture thread which is supplied sterile. It is composed of isotactic polypropylene polymer, and is indicated for soft tissue approximation. It will be offered undyed, and dyed with the FDA approved colorant [Phthalocyaninati(2-)] copper in accordance with Title 21 CFR, §74.3045. It will be available with and without standard needles attached.

## E. Intended Use

*Premilene* Nonabsorbable Polypropylene Surgical Sutures are indicated for use in all types of general soft tissue approximation and ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.

## F. Comparison to Predicate Devices

The subject *Premilene* Nonabsorbable Polypropylene Surgical Suture is composed of the same material as are the predicate devices, that being the isotactic form of the polyolefin polymer polypropylene. Further, the subject device is offered undyed, and dyed with the same colorant as are the predicate devices, that being {phthalocyaninato(2-)] copper at a concentration of ≤0.5% by suture weight in accordance with Title 21 CRR, §74.3045.

The subject device has the same design as do the predicate devices, being a sterile, flexible monofilament 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, elasticity, and needle attachment strength.

The subject device is manufactured in the same manner as at least one of the predicate devices, being supplied to Aesculap® by the manufacturer of said predicate suture. As such, the suture fiber from which the subject device is made has the same chemical characteristics, biocompatibility profile, and *in vivo* performance properties as does that predicate device.

The subject device is packaged and sterilized in the same or equivalent manner, and has the same labeling claims as do the predicate devices, including indications, contraindications, warnings, cautions and precautions.

## G. Summary of Non-Clinical Tests

Non-Clinical testing conducted on the subject device to demonstrate its substantial equivalence to predicate devices included physical testing for all parameters identified above, sterilization validation and evaluation of sterilant residues, and shelf-life testing. Testing conducted by the manufacturer and supplier to Aesculap® of the finished suture fiber included chemical assays for identity and purity, testing of physical properties 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

MAY 4 1998

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

Re: K980703
Premilene Nonabsorbable Polypropylene Surgical Suture
Dated: February 19, 1998
Received: February 23, 1998

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 Premilene Nonabsorabable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery, and neurological procedures.

2. This device may not be manufactured from any material other than a long chain polyolefin polymer known as polypropylene. 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 Polypropylene 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) 594-4595. 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,

for 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

510(k) Number (if known): K980703

Device Name: *Premilene*® Nonabsorbable Polypropylene Surgical Suture

**Indications For Use:**

*Premilene® sutures are indicated for use in all types of general soft tissue approximation and ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980703

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____