4/30/99

K991223

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

AESCULAP®
1000 Gateway Boulevard
South San Francisco, California 94080-7030
Telephone: (415) 876-7000
Contact: Victoria Mackinnon, Director of Regulatory Affairs & Quality Assurance
Date Prepared: April 6, 1999

B. Device Name

Trade or Proprietary Name:	Absorbable Surgical Gut Suture, plain and chromic; *Softcat*® Absorbable Surgical Gut Suture, plain and chromic
Common or Usual Name:	Absorbable Surgical Gut Suture, plain and chromic
Classification Name:	Absorbable Surgical Gut Suture

C. Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- Plain and Chromic Absorbable Surgical Suture (Davis & Geck))
- Plain and Chromic Absorbable Surgical Suture (Ethicon, Inc.)
- SOFTGUT® Plain and Chromic Absorbable Surgical Suture (Davis & Geck)
- SURGIGUT® Plain and Chromic Absorbable Surgical Gut Suture (U.S. Surgical Corporation)

D. Device Description

The subject device is an absorbable, flexible suture thread, available in both plain and chromicized forms, which is supplied sterile. It is manufactured from the serosal connective tissue layer of bovine intestine or the submucosal layer of ovine intestine. It is indicated for general soft tissue approximation and/or ligation, including ophthalmic tissues, but not including cardiovascular or neural tissues. It is undyed, and is available with and without needles attached. In the *Softcat*® form, both plain and chromic sutures are treated with glycerol.

E. Intended Use

AESCULAP® Absorbable Surgical Gut Sutures and *Softcat*® Absorbable Surgical Gut Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including ophthalmic procedures, but not for use in cardiovascular or neural tissue.

F. Comparison to Predicate Devices

The subject Absorbable Surgical Gut Suture is composed of processed strands of bovine serosa or ovine submucosa, materials equivalent, if not identical, to those comprising the predicate sutures. The subject device is offered both plain, and chromicized to prolong its *in vivo* strength retention. In addition, the *Softcat*® plain and chromic forms of the subject device have been treated with a glycerol solution to enhance handling properties, in the same fashion as the predicate Davis & Geck SOFTGUT® suture.

The subject device has the same design as do the Ethicon and Davis & Geck predicate devices, being a sterile, flexible thread available in sizes 6-0 (1 Metric) through 4 (8 Metric), being offered with or without one of a selection of standard needles attached, and conforming in all respects to the requirements of the Official Monograph for Absorbable Surgical Suture in U.S.P. XXIII, including <861> *Sutures -- Diameter*, <871> *Sutures -- Needle Attachment*, and <881> *Tensile Strength.*.

As is also the case with the predicate devices, the sutures are offered either plain, or treated with a chromic salt and cross-linked to increase resistance to degradation *in vivo*, thereby prolonging tensile strength retention. Both plain and chromic sutures are offered in traditional packaging containing an alcohol solution to prevent spruing caused by drying during storage.

Alternatively, as is the case with the predicate Davis & Geck SOFTGUT® sutures, *Softcat*® plain and chromic sutures are treated with a glycerol solution before packaging to prevent spruing and to preserve handling properties.

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

The subject device is manufactured in a manner typical of the industry, and equivalent to that used to produce predicate devices, wherein bovine serosa or ovine submucosa are harvested from healthy animals, cut into long strips which are cleaned mechanically and chemically to remove non-collagenous materials, twisted together to form monfilament-like strands, dried, polished to uniform diameter, cut to length, and attached to needles to make finished sutures. A series of chromicizing and cross-linking baths are added to the process to make chromic sutures, and both plain and chromic sutures are either packaged in an alcohol solution to prevent fiber drying during storage, or treated with a glycerol solution to condition the fibers before packaging. Given that the subject device is made from the same materials, and in essentially the same fashion, as the Ethicon and Davis & Geck predicate devices, the subject device can be expected to have the same or equivalent chemical characteristics, physical properties, biocompatibility, and *in vivo* performance properties as do the predicate devices.

The subject device is packaged and sterilized in the same or equivalent manner, and has the same or equivalent 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 testing of physical properties to prove conformance to the requirements of U.S.P., *in vitro* and *in vivo* biosafety studies, implant studies in animals to demonstrate rates of tensile strength and mass loss, and shelf life and sterilization validation studies.

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

APR 30 1999

AESCULAP
c/o Mr. Steve Reitzler, RAC
13221 Maricotte Place
San Diego, California 92130

Re: K991223
Trade Name: Absorbable Surgical Gut Suture, and SOFTCAT® Absorbable Surgical Suture
Regulatory Class: II
Product Code: GAL
Dated: April 6, 1999
Received: April 12, 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 Monday, December 11, 1989 (Vol. 54, No. 236, Pages 50737 and 50738). 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 Absorbable Surgical Gut Suture and SOFTCAT® Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

2. This device may not be manufactured from any material other than serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine. 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 manufacturing of the Absorbable Surgical Gut Suture and SOFTCAT® Absorbable Surgical Suture. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

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 registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, 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,

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): K991223

Device Name: AESCULAP® Absorbable Surgical Gut Suture

Indications for Use:

Absorbable Surgical Gut Suture is indicated for use in general soft tissue approximation and/or ligation , including use in ophthalmic procedures, but not for use in cardiovascular or neural tissues.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991223

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____