K981322

JUL 7 1998

Section 2 510(k) Summary

510(k) Summary
Genzyme "Cutalon" Nonabsorbable Polyamide Surgical Suture

1. DATE PREPARED

April 7, 1998

2. SPONSOR INFORMATION

Address: Genzyme Surgical Products
600 Airport Road
Fall River, Massachusetts 02720

Telephone: 508-677-6679

Contact: Jim Kenney
Director, Quality Assurance/Regulatory Affairs

3. DEVICE NAME

Proprietary Name: "Cutalon" Nonabsorbable Polyamide Surgical Suture
Common/Usual Name: Nylon Nonabsorbable Polyamide Suture
Classification Name: Nylon Nonabsorbable Polyamide Suture

4. DEVICE DESCRIPTION AND INTENDED USE

"Cutalon" Nonabsorbable Polyamide Surgical Sutures are composed of the long-chain aliphatic polymers extruded Nylon (Nylon 6) sutures which conform to the United States Code of Federal Regulations, 21 CFR Part, 878.5020.

"Cutalon" Nonabsorbable Polyamide Surgical Sutures are provided sterile and are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

5. COMPARISON TO PREDICATE DEVICE(S)

"Cutalon" Nonabsorbable Polyamide Surgical Sutures are identical in design, material, manufacturing process, function, and intended use to Nylon (Nylon 6) Nonabsorbable Surgical Sutures which are have been marketed by the Sponsor Company since 1976.

Section 3 Proposed Labeling

Draft proposed labeling for the "Cutalon" Nonabsorbable Polyamide Surgical Suture includes the actual device labeling and the package insert. Sample draft labeling for the device is provided in Appendix A.

Section 4 Device Description

"Cutalon" is a wet-packed, extruded, nylon monofilament suture. The base polymer material is Nylon 6. (As required in CFR 878.5020) The nylon suture material is foil-packaged "wet" in a solution containing isopropyl alcohol, water and other components (see below description of formulation).

The packaging fluid contains: Isopropyl Alcohol 73.65%
1,2-Propylene Glycol 15.00%
Water 8.25%
Glycerin 2.30%
Lactic Acid 0.45%
Diethanolamine 0.20%
Sodium Nitrite 0.10%
Ammonia 0.05%

The purpose of the "wet" packaging is to provide a nylon suture that is supple (easier to twist and tie) straight from the package due to the water absorption into the nylon.

Genzyme "Cutalon" Surgical Suture are available in USP sizes 6-0 through 0 (metric sizes 0.7 through 3.5). Genzyme Cutalon Sutures meet all requirements established by the United States Pharmacopeia (USP) for nonabsorbable sutures except for diameter.

The "Cutalon" Suture is identical in design, materials (Nylon 6), manufacturing process and intended use to the Nylon Suture already marketed by Genzyme Surgical Products. This "Cutalon" Suture is simply a change in the packaging.

Genzyme's Nylon Suture has been on the market since December 1976. In Appendix D, please see a copy of NDA 85-060 FDA letter from December 1976 and also see a copy of the FDA's 510(k) letter dated July 26, 1994 which confirms that Genzyme has followed the instructions for "Suture Labeling Guidance" dated October 9, 1992.

Design, Materials, Process, Packaging

The "Cutalon" Suture is designed to maintain sterility of the product until the time of use. Each individual suture/needle assembly is wrapped around a plastic winder and the combination is placed inside an open-ended pouch. The suture assemblies in their pouches are then loaded into the packaging machine. This machine forms a polyethylene "blister" and seals a medical grade paper lid stock onto it after it is filled with packaging fluid and product. The sealed blister is placed into a purchased film/Tyvek pouch and sealed on a bar sealer. (The bar sealers were validated for outer pouch sealing for the "wet" products and a packaging machine was validated for wet packed inner blister packaging.
The pouch is designated to allow sterilization with the pouch and maintain a sterile environment until the pouch is opened. The Cutalon Nylon suture is foil-packaged "wet" in a solution containing isopropyl alcohol, water and other components. The purpose once again of the "wet" packaging is to provide a Nylon suture that is supple (easier to twist and tie) straight from the package due to the water absorption into the nylon.

The "wet" pouches are placed into solid bleached sulfite board boxes, with instructions for use. Polyamide suture packages are opened by peeling open the pouch. The loaded carrier is then aseptically opened in the sterile field. There is a clear film overwrap applied to the shelf box as a dust cover. Outer corrugate shipping cartons of various sizes are used to ship the suture boxes.

STERILIZATION:

a.	Sterilization Method:	Gamma Irradiation (Cobalt 60)
b.	Validation Method:	AAMI/ANSI/ISO 11137 Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization.
c.	Sterility Assurance Level	10^{-6}

Section 5 Substantial Equivalence and Comparison Information

The "Cutalon" Nonabsorbable Polyamide Surgical Suture is identical in design, materials, manufacturing process, function and intended use to the predicate device, Genzyme's Nylon Suture.

Genzyme's Nylon Suture has been on the market since December 1976. In Appendix C, please see a copy of NDA 85-060 FDA letter from December 1976 and also see a copy of the FDA's 510(k) #K930738 letter dated July 26, 1994 which confirms that Genzyme has followed the instructions for "Suture Labeling Guidance" dated October 9, 1992.

Table 1
"Cutalon" Nylon Sutures Compared to Predicate Suture Product

	"Cutalon" Suture	**Nylon Suture**
Intended Use	General soft tissue approximation and/or ligation	General soft tissue approximation and/or ligation
Suture Material	Nylon 6 or 6.6	Nylon 6 or 6.6
Sterilization Method	Gamma Irradiation	Gamma Irradiation or ETO
How provided	Sterile for Single Use Only	Sterile for Single Use Only
USP Sizes	6-0 thru 0	10-0 thru 5
Suture Tensile Strength	Meets USP Requirement	Meets USP Requirement
Packaging	Wet Packaged (sterile)	Dry Packaged (sterile)

Section 6 Biocompatibility Information

Biocompatibility testing was performed on Genzyme "Cutalon" Nylon Surgical Sutures which satisfied the requirements of ISO 10993-1 Biological Evaluation of Medical Devices. The biocompatibility tests conducted were:

- USP Muscle Implant (1 week)
- USP Muscle Implant (90 days)
- USP Physico-Chemical
- Sensitization (saline and CSO)
- USP Intracutaneous Testing (saline and CSO)
- Acute Systemic Toxicity
- Hemocompatibility
- Cytotoxicity (USP Elution Method)
- Genotoxicity (DMSO extract)
- Genotoxicity (Saline extract)

The results of the biocompatibility testing of Genzyme "Cutalon" Nylon Surgical Sutures show the sutures to be non-cytotoxic, non-hemolytic, non-allergenic, non-mutagenic, non-irritant, meeting requirements for systemic toxicity, meeting implant requirements, and meeting USP requirements for long-chain aliphatic polymer Nylon 6. Reference Appendix D for copies of the actual test reports.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Genzyme Surgical Products
Mr. Stephen M. Page
Director of Regulatory Affairs
600 Airport Road
Fall River, Massachusetts 02720

JUL 7 1998

Re: K981322
Trade Name: "Cutalon" Nylon Polyamide Surgical Suture
Regulatory Class: II
Product Code: GAR
Dated: April 8, 1998
Received: April 10, 1998

Dear Mr. Page:

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 "Cutalon" Nylon Polyamide 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 long chain aliphatic polymers other than nylon 6 and/or nylon 6,6. 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 "Cutalon" Nylon Polyamide 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.

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,

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

K981322

Device Name: "Cutalon" Nonabsorbable Polyamide Surgical Suture

Indications for Use:

"Cutalon" Nonabsorbable Polyamide Surgical Sutures are provided sterile and are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

These indications for use are exactly the same as for the device we have on the market, Nylon Nonabsorbable Polyamide Surgical Sutures. The Nylon suture was approved for marketing by way of PreMarket Approval Application (PMA) # N85-060 "Approval Letter" for the original PMA dated July 26, 1976.

The only change between "Cutalon" and Nylon is the method of packaging. Nylon is dry packaged. "Cutalon" is wet packaged. [The difference is explained in detail in the body of this 510(k)].

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(K) Number K981322

Genzyme Surgical Products
600 Airport Road
Fall River, Massachusetts 02720-4740

Prescription Use X
(Per 21 CFR 801.109)