

K970863

**UNITED STATES SURGICAL CORPORATION  
510(k) PREMARKET NOTIFICATION  
Modified USSC\* POLYSORB\* Suture\*\***

MAY - 5 1997

**SUMMARY      510(K) SUMMARY OF INFORMATION SUPPORTING  
SAFETY AND EFFECTIVENESS**

**SUBMITTER:** United States Surgical Corporation  
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**CONTACT PERSON:** Jonathan Gilbert

**DATE PREPARED:** March 6, 1997

**CLASSIFICATION NAME:** Absorbable Surgical Suture

**COMMON NAME:** Synthetic Absorbable Surgical Suture

**PROPRIETARY NAME:** The trademark name of this device has not yet been determined.

**PREDICATE DEVICE:** USSC\* Braided Synthetic Absorbable Suture\*\* (K961997) and USSC\* POLYSORB\* Sutures (K963253)

**DEVICE DESCRIPTION:** Modified USSC\* POLYSORB\* sutures are composed of LACTOMER\* glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). The suture is coated with a mixture of caprolactone/glycolide copolymer and calcium stearoyl lactylate.

**INTENDED USE:** Modified USSC\* POLYSORB\* Sutures are indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.

**MATERIALS** Modified USSC\* POLYSORB\* sutures are composed of LACTOMER\* glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids).

**PERFORMANCE:** Meets the requirements of U.S.P. Synthetic Absorbable Suture Monograph for tensile strength, needle attachment and diameter.

\*Trademark of United states Surgical Corporation  
\*\*Trademark name not yet determined