

United States Surgical Corporation
510(k) Premarket Notification
modified SOFSILK* Suture

JAN 16 1997

510(k) SUMMARY OF INFORMATION:

K964581

SUBMITTER: United States Surgical Corporation
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Norwalk, CT 06856
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CONTACT PERSON: Janet G. Johnson

DATE PREPARED: October 31, 1996

CLASSIFICATION NAME: Natural Nonabsorbable Silk Surgical Suture

COMMON NAME: Nonabsorbable Silk Suture

PROPRIETARY NAME: SOFSILK*

PREDICATE DEVICE: SOFSILK* (K900840, K902874 and K903509) ^{PR}

DEVICE DESCRIPTION: SOFSILK* suture is a nonabsorbable, sterile, flexible multifilament thread, prepared from silk fiber produced by the species *Bombyx mori*. The primary component of silk is the high molecular weight fibrous polymer *fibroin*.

INTENDED USE: Due to its nonabsorbable nature, SOFSILK* suture is intended for the approximation of tissues where prolonged retention of tensile strength is required.

MATERIALS: All component materials of the SOFSILK* suture are comprised of materials which are in accordance with ISO Standard #10993-1.