K962480

SECTION 7

AUG - 2 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: Additional size of Coated VICRYL *RAPIDE** (polyglactin 910) braided synthetic absorbable suture, undyed, Size 6-0.

PREDICATE DEVICE NAME: Coated VICRYL *RAPIDE* (polyglactin 910) braided synthetic absorbable suture, undyed.

510(k) SUMMARY

Device Description

6-0 Coated VICRYL *RAPIDE* (polyglactin 910) suture, undyed is a sterile suture, flexible multifilament strand prepared from a copolymer made from glycolide and lactide. The coating for 6-0 undyed VICRYL *RAPIDE* is prepared with a mixture of copolymer of glycolide and L-lactide and calcium stearate.

Intended Use

6-0 undyed VICRYL *RAPIDE* suture is intended for use in superficial general soft tissue approximation where only short term wound support is required.

Size 6-0 Coated VICRYL *RAPIDE* suture, undyed has the same intended use as the predicate device.

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510(k) SUMMARY, Continued

Indications Statement	6-0 undyed Coated VICRYL *RAPIDE* suture is indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Coated VICRYL *RAPIDE* suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.
Technological Characteristics	6-0 Coated VICRYL *RAPIDE* suture, undyed has the same technological characteristic as the predicate device. There is no change in chemistry, material or composition.
Performance Data	Benchtop testing was performed to assess knot tensile strength and nonclinical laboratory testing was performed to determine breaking strength retention. Biocompatibility and clinical was deemed unnecessary to support this modification.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
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