DEC 18 1996

SECTION 7 K964072

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: MONOCRYL (poliglecaprone 25) suture, undyed

PREDICATE DEVICE NAME: MONOCRYL (poliglecaprone 25) suture, dyed

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510(k) SUMMARY

Device Description

MONOCRYL suture, undyed is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone.

Intended Use

MONOCRYL suture, undyed is intended for use in general soft tissue approximation and/or ligation.

MONOCRYL suture, undyed has the same intended use as predicate device MONOCRYL suture, dyed.

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510(k) SUMMARY, Continued

Indications Statement	Modified MONOCRYL sutures, undyed are indicated for soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.
Technological Characteristics	The modified device has the same technological characteristics as the predicate device. There is no change in material or chemical compound. Modified MONOCRYL suture, undyed has an increased breaking strength retention (BSR) profile identical to the predicate device.
Performance Data	Nonclinical laboratory testing was performed to determine breaking strength retention profile after implantation. It was determined that the BSR profile for Modified MONOCRYL suture, undyed is identical to the predicate device.
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.
Contact	John D. Paulson, Ph.D. Vice President, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
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