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SECTION 7

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.

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

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

510(k) SUMMARY

Device Description

MONOCRYL suture, dyed is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone. MONOCRYL suture is dyed violet using D&C Violet No. 2.

Intended Use

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

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

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement	MONOCRYL sutures, dyed 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 chemistry, material or composition. When compared to the predicate device, dyed MONOCRYL suture, MONOCRYL suture, dyed has an increased breaking strength retention (BSR) profile.
Performance Data	Nonclinical laboratory testing was performed to determine breaking strength retention. Biocompatibility and clinical was deemed unnecessary to support this labeling change.
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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