

K964345

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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: ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed

PREDICATE DEVICE: VICRYL* (Polyglactin Suture)

REFERENCE DEVICE NAMES: Predicate device Johnson & Johnson Absorbable Tendon Suture and Coated VICRYL* II (Polyglactin 910) suture.

510(k) SUMMARY

Device Description

Synthetic ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is a synthetic braided absorbable surgical suture prepared from a copolymer of lactide and glycolide. The suture is coated with a copolymer of caprolactone and glycolide.

Intended Use

ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is intended for use in general soft tissue approximation and/or ligation as is the predicate device Coated VICRYL* (Polyglactin 910) suture.

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ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed
ETHICON, Inc.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement

ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is indicated for soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular, or neurological tissue.

Technological Characteristics

The new device has similar technological characteristics as the predicate device Coated VICRYL (Polyglactin 910) suture. The new device has the same chemical composition as the reference device, Absorbable Tendon Suture.

When compared to the predicate devices, ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed, Undyed increased breaking strength retention (BSR) and absorption profile.

Performance Data

Nonclinical laboratory testing was performed to determine breaking strength retention. Biocompatibility and Functionality testing was conducted to assess the safety and effectiveness of ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed. Results indicated that the device was highly biocompatible and was functional within its indicated uses.

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 Devices under the Federal Food, Drug, and Cosmetic Act.

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ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed
ETHICON, Inc.