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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: Modified PROLENE* polypropylene mesh nonabsorbable synthetic surgical mesh

PREDICATE DEVICE NAME: PROLENE* polypropylene mesh nonabsorbable synthetic surgical mesh

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510(k) SUMMARY

Device Description

Modified PROLENE mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE suture nonabsorbable surgical sutures, U.S.P. (ETHICON, INC.). The mesh is approximately 0.027 inches thick. This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use.

Intended Use

Modified PROLENE mesh is intended for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material, to obtain the desired surgical result.

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510(k) SUMMARY, Continued

Intended Use (continued)	Modified PROLENE mesh has the same intended use as the preamendment predicate device PROLENE mesh.
Indications Statement	Modified PROLENE mesh is intended for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material.
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, Modified PROLENE mesh differs in the additional sizes that are being supplied and a key hole shape which is being provided precut as a convenience to the surgeon.
Performance Data	Burst strength testing was conducted to compare the predicate device and the modified device.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

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