K965038

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VI. Premarket Notification 510(k) Summary

A. Submitter: W.L. Gore and Associates, Inc.
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B. Applicant Devices:

Names of Devices with Modified Labeling

GORE-TEX® Soft Tissue Patch PLUS
GORE-TEX® DualMesh PLUS Biomaterial
GORE-TEX® MycroMesh PLUS Biomaterial
GORE-TEX® DualMesh PLUS Biomaterial with Holes

C. Applicant Devices Description:

Inert, biocompatible, expanded polytetrafluoroethylene (ePTFE) loaded with the antimicrobial preservative agents silver carbonate and chlorhexidine diacetate.

D. Indications For Use:

The devices are indicated for use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

E. Predicate Devices:

The following devices, loaded with antimicrobial preservative agents, are cited as substantially equivalent predicate devices concerning possible adverse reactions, materials, design, biocompatibility, mechanical strength, manufacturing, packaging, sterilization, antimicrobial activity and preservative efficacy:

GORE-TEX® Soft Tissue Patch PLUS
GORE-TEX® DualMesh PLUS Biomaterial
GORE-TEX® MycroMesh PLUS Biomaterial
GORE-TEX® DualMesh PLUS Biomaterial with Holes

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The following devices, without antimicrobial preservative agents, are cited as substantially equivalent predicate devices which contain the same indications for use statement:

GORE-TEX® Soft Tissue Patch
GORE-TEX® DualMesh Biomaterial
GORE-TEX® MycroMesh Biomaterial
GORE-TEX® DualMesh Biomaterial with Holes

F. Technological Characteristics:

This Premarket Notification submission is for a modification to the indications for use for the applicant devices. The applicant devices are not being changed in any way (except for labeling) as a result of this submission's clearance. The materials, design and performance characteristics for the applicant devices have not changed from those of the predicate devices. There are no new technological characteristics due to the modification of the indications for use.

G. Safety and Effectiveness Conclusions:

This Premarket Notification concerns a modification to the indications for use for currently marketed, previously cleared surgical mesh devices. Therefore, the applicant devices are the same, and consequently, substantially equivalent to the predicate devices with regard to possible adverse reactions, materials, design, biocompatibility, preservative effectiveness, antimicrobial activity, mechanical strength, packaging, manufacturing process and sterilization process.

The applicant devices and the predicate devices have the same intended use as prostheses for permanent or temporary wound or defect support. Each of the devices perform their equivalent clinical functions by incorporating biocompatible materials to permanently or transiently bridge or support a tissue defect.

The modification of the indications for use for the applicant devices does not raise questions of safety or effectiveness that have not been previously addressed.