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VI. Premarket Notification 510(k) Summary

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B. Device Name: GORE-TEX® DualMesh PLUS Biomaterial with Holes

C. Applicant Device Description:

Biocompatible, expanded polytetrafluoroethylene (ePTFE) with antimicrobial preservative agents in a flat sheet configuration of various length and width dimensions. Macropores are placed in the device in order to optimize rapid tissue fixation.

D. Indications For Use:

An implantable surgical mesh prosthesis indicated for the reconstruction of hernias and soft tissue deficiencies.

E. Predicate Devices:

Gore's surgical mesh products, GORE-TEX® DualMesh PLUS Biomaterial and GORE-TEX® DualMesh Biomaterial with Holes, are cited as predicate devices which have been found to be substantially equivalent through the premarket notification process.

F. Technological Characteristics:

The applicant device integrates the clinically successful attributes of GORE-TEX® DualMesh PLUS Biomaterial and GORE-TEX® DualMesh Biomaterial with Holes into a single device through the manufacture of macropores into GORE-TEX® DualMesh PLUS Biomaterial.

The applicant device is manufactured using the same inert, biocompatible ePTFE material as the predicate devices. The antimicrobial preservative agents loaded into the applicant device are the same, and are loaded in the same amounts, as for the previously cleared GORE-TEX® DualMesh PLUS Biomaterial. The macropores manufactured into the applicant device have the same dimensions and are created using the same process as the macropores in the previously cleared GORE-TEX® DualMesh Biomaterial with Holes.

Mechanical strength values of the applicant device are substantially equivalent to the mechanical strength values of the predicate devices and are sufficient for its indicated uses.

	Applicant Device	
Suture Pull-Out Force (kg/5 pins)	Mean	Std Dev
Low Rate	7.7	0.5
High Rate	8.2	0.7
Tensile Force to Break (kg/0.5")	8.3	0.3

G. Safety and Effectiveness Conclusions:

The applicant device is indicated for use in clinical applications which have previously been cleared for the predicate devices.

The applicant device is manufactured of the same inert, biocompatible expanded PTFE and the same antimicrobial preservative agents as the previously cleared GORE-TEX® DualMesh PLUS Biomaterial.

Macropores are created in the applicant device utilizing the same manufacturing process and technology as used for creating macropores in the previously cleared GORE-TEX® DualMesh Biomaterial with Holes.

The packaging materials and process used for the applicant device do not differ from those used for the predicate devices. The applicant device is sterilized using the same sterilization methods and utilizes the same post-sterilization release criteria as the predicate devices.

The applicant device has been shown via bench testing to have mechanical strength values substantially equivalent to the mechanical strength values of the predicate devices.

Combining clinical features from each of the previously cleared predicate devices into GORE-TEX® DualMesh PLUS Biomaterial with Holes does not compromise the safety or effectiveness of the applicant device. The manufacturing of macropores into the predicate GORE-TEX® DualMesh PLUS Biomaterial does not raise new types of safety or effectiveness questions. The descriptive and mechanical strength information contained within this Premarket Notification document are precise enough to demonstrate the substantial equivalency of GORE-TEX® DualMesh PLUS Biomaterial with Holes.