OCT 25 1996

K963619

Premarket Notification Summary

1. **Applicant:** W. L. Gore and Associates, Inc.
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Contact: John W. Nicholson, Associate
Date of Preparation: 09/06/96

2. a) **Applicant Devices:** GORE-TEX® Soft Tissue Patch
GORE-TEX® MycroMesh Biomaterial
GORE-TEX® DualMesh Biomaterial
GORE-TEX® DualMesh Biomaterial with Holes

b) **Common Name:** Surgical Mesh

c) **Classification Name:** Surgical Mesh

3. **Predicate Devices:**

GORE cites the following as substantially equivalent predicate devices:

GORE-TEX® Soft Tissue Patch
GORE-TEX® MycroMesh Biomaterial
GORE-TEX® DualMesh Biomaterial
GORE-TEX® DualMesh Biomaterial with Holes
Davis & Geck DEXON Mesh K 830889
Ethicon Vicryl Woven Mesh K 810428

4. **Device Description:**

The applicant GORE surgical meshes are not being changed in any way (except for labeling) as a result of this submission's clearance. The proprietary manufacturing process that GORE's surgical meshes undergo creates a pattern of solid nodes of PTFE interconnected by a latticework of PTFE fibrils. The staggering of these nodes and fibrils and the pattern of these structures produces a microstructure which determines the degree and celerity with which tissue attachment occurs. More than 4,000,000 implants of GORE-TEX® ePTFE Medical Products in vascular, cardiac, dural and a broad variety of general surgery applications during the past two decades have established a substantial body of knowledge and experience relating to the biocompatibility and performance of ePTFE. A selected bibliography is provided in **Attachment 5.**

5. **Intended Use:**

The applicant devices are intended to be used for the reconstruction of hernias and for the temporary bridging of fascial defects and soft tissue deficiencies.

6. **Technological Characteristics:**

The Table below presents some of the basic comparative characteristics of the applicant device and its cited predicate devices.

GORE-TEX® Soft Tissue Patch	For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects, such as omphaloceles	ePTFE	FTL
GORE-TEX® MycroMesh Biomaterial	For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects, such as omphaloceles	ePTFE	FTL
GORE-TEX® DualMesh Biomaterial	For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects, such as omphaloceles	ePTFE	FTL
GORE-TEX® DualMesh Biomaterial with Holes	For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects, such as omphaloceles	ePTFE	FTL
Davis & Geck DEXON Mesh	For use when temporary wound support is required	Polyglycolic Acid	FTM
Ethicon VICRYL Woven Mesh	For use as a buttress to provide temporary support during the healing process	Polyglactin 910	FTL

The applicant and predicate devices have the same intended use as prostheses for temporary wound or defect support and are classified as surgical meshes. They achieve their equivalent clinical functions by incorporating biocompatible materials to transiently bridge or support a tissue defect. Although not all these devices incorporate the same technological characteristics (i.e.materials), however, the fact that these biomaterials individually have extensive and successful clinical histories indicate that this change of material type does not pose new safety or effectiveness questions. The performance data or clinical experience with GORE-TEX® ePTFE usage in temporary soft tissue deficiencies presented above (Published Clinical Data) describes the successful clinical performance of the devices in a variety of populations. These factors combined provide the basis for a substantial equivalency determination when comparing the applicant devices with their cited predicates.