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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Applicant Name, Address:** W.L. Gore & Associates, Inc.
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2. **Classification Name:** Resorbable Barrier Membrane
Common or Usual Name: Regenerative Material
Proprietary Name: RESOLUT Regenerative Material

3. **Predicate Device** RESOLUT Regenerative Material, CAPSET Calcium Sulfate Bone Graft Barrier, and Micro Titanium Augmentation Mesh.

4. **Device Description:**

RESOLUT Regenerative Material is composed of a porous structure of synthetic bioabsorbable glycolide polymer fiber and an occlusive membrane of synthetic bioabsorbable glycolide and lactide copolymer. The porous structure is designed to attach to surrounding soft tissue and inhibit epithelial migration, while the occlusive membrane isolates the periodontal defect from gingival connective tissue during wound healing. RESOLUT Regenerative Material has been designed to act in accordance with the accepted principles of wound healing and guided tissue regeneration (GTR). Specifically, the device is designed to be biocompatible, cell occlusive, spacemaking, and clinically manageable, and allow for tissue integration.

RESOLUT Regenerative Material is surgically placed beneath the muco-periosteum to aid in the regenerative healing of bone/periodontal ligament defects of the oral cavity or, when placed over bone graft material, to prevent graft material migration.

5. **Intended Use**:

RESOLUT Regenerative Material is a bioabsorbable, implantable material intended to aid in the healing of periodontal defects. It may also be used as a membrane for bone graft containment. When used over a bone graft, RESOLUT Regenerative Material provides a stable barrier to graft material migration and provides a favorable environment for bone regeneration.

6. **Technological Characteristics**:

RESOLUT Regenerative Material has been designed to act in accordance with the accepted principles of wound healing and guided tissue regeneration (GTR). Specifically, the device is designed to be biocompatible, cell occlusive, spacemaking, and clinically manageable, and allow for tissue integration.

7. **Assessment of Performance Data**:

A preclinical study in canine mandibular defects demonstrates that RESOLUT Regenerative Material can be used as a membrane to contain bone grafting materials. Like CAPSET Calcium Sulfate Bone Graft Barrier, it has been shown to provide a favorable environment for bone regeneration.

In the first clinical study, the investigators used a comparative histological study to evaluate the regenerative capabilities of both resorbable and non-resorbable barrier membranes in defects associated with endosseous implant placement. Additionally, they included untreated controls (i.e., no barrier membrane) in this study. They found that there was bone regeneration in the membrane-treated sites, but there was more in the defects treated with the non-resorbable barrier

membrane. However, they concluded that "to achieve complete regeneration, it may be necessary to use resorbable membranes in association with osteoconductive/osteoinductive space maintaining material, such as autogenous grafts". The importance of the first clinical study is that it provides histological evidence of bone regeneration.

The second clinical study tests their hypothesis further and utilized autogenous bone grafts to maintain an adequate space under the barrier membranes. The overall study results showed a highly significant reduction in defect ($p < 0.001$), with an average bone fill per defect of 93%. This study provides confirmatory evidence that barrier membranes, when used as membranes for bone graft containment, provides a favorable environment for bone regeneration.

8. **Conclusion**:

There have been no changes to RESOLUT Regenerative Material in terms of its design, manufacturing process, materials, and intended use. The modifications to the indications for use are substantially equivalent to the indications for use of CAPSET Calcium Sulfate Barrier Graft, Micro Titanium Augmentation Mesh, and the predicate RESOLUT Regenerative Material.