5. 510(k) Summary

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Trade name	Endoform® Restella - Absorbable and Non-Absorbable
Common name	Surgical mesh
Classification name	Mesh, Surgical; Mesh, Surgical Polymeric
Predicate device	Endoform® Plastics & Reconstruction Matrix (K162461)

5.1 Device Description

Endoform Restella is a surgical mesh manufactured by layering sheets of ovine forestomach matrix to create multi-layer configurations of devices laminated with absorbable polyglycolic acid (PGA) and non-absorbable polypropylene (PP) suture material for use in plastic and reconstructive surgery. The 3-ply devices are available in sizes up to 400 cm^2 in arced rectangle, contour, and oval shapes.

5.2 Intended Use and Indications for Use

5.2.1 Intended Use

Endoform Restella is intended for use in the reinforcement of soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastics and reconstructive surgery.

5.2.2 Indications for Use

Endoform Restella is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

5.3 Technological Characteristics Comparison

Endoform Restella devices are a line extension to Endoform Reconstructive Template devices embroidered with either absorbable polyglycolic acid (K130547) or non-absorbable polypropylene suture (K153632) to introduce new configurations for use in plastic and reconstructive surgery.

Endoform Restella maintains the same fundamental technological characteristics as the predicate device, Endoform® Plastics & Reconstruction Matrix (K162461) with respect to material composition, biocompatibility, sterilization, and packaging materials and processes. The primary difference is the lamination method in that the subject device is embroidered with either polyglycolic acid and polypropylene suture material, while the predicate contains no suture material and is laminated using a proprietary lugging method.

Performance and validation testing executed based on risk analysis of the design changes supports substantial equivalence of the subject device. The primary characteristic specifications for the ovine forestomach matrix have not changed as a result of the modification. However, the Restella device may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs

5.4 Non-Clinical Performance Data

The bench testing and validation conducted on Restella devices demonstrates substantial equivalence to the predicate device. Bench testing included mechanical strength, endotoxin, and dimensional verification testing. Results of the testing confirms that the proposed device meets all product specifications for the intended use.

Previous biocompatibility testing performed for the product presented in K153632 remains applicable to Restella based on the equivalence of the material composition of the proposed device to the predicate.

5.5 Clinical Performance Data

Substantial equivalence was not based on an assessment of clinical performance data.

5.6 Conclusions

The technological characteristics and materials of the subject device are equivalent to the predicate. Based on the results of verification and validation testing it can be concluded that the proposed device is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness