

Kugel Hernia Patch™ 510(k) Summary

In accordance with 21 CFR section 807.92 Surgical Sense, Inc. is submitting the following safety and effectiveness summary.

1) Submitter Information

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2) Name of Device

Proprietary Name: Kugel Hernia Patch™
Common Name: Surgical Mesh
Classification Name: Surgical Mesh

3) Substantially equivalent to Atrium Polypropylene Mesh

4) The Kugel Hernia Patch™ is a surgical mesh for reinforcement of a hernia defect.

5) The intended use of the Kugel Hernia Patch™ is a surgical mesh for hernia repair. It is indicated for use in all forms of hernia repair. A few examples of hernia repair are Inguinal, Femoral, Incisional and Ventral hernia repairs in the abdominal wall and the groin area.

6) The Kugel Hernia Patch™ is equivalent to the Atrium Polypropylene Mesh in that it has the same intended use (hernia repair), the same material (polypropylene mesh) and the same sterilization method (EtO).

The Kugel Hernia Patch™ has been designed using materials from existing medical devices. The following tests and validation have been or will be performed on the Kugel Hernia Patch™:

- Biocompatibility per ANSI/AAMI/ISO 11135-1994
- Sterility validation per ANSIAAMI/ISO 11135-1994
- Sterility testing per industry accepted protocols
- LAL testing per industry accepted test protocols
- Packaging integrity process validation
- NTSB shipping durability test