510(k) Summary

Device Common Name: Dressing, Wound, Drug

Device Proprietary Name: SilverSeal®

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Date Prepared: March 31, 2017

Classification Regulation: Unclassified, pre-amendment

Panel: General & Plastic Surgery

Product Code: FRO

Predicate Device: K040019 – X-Static® SilverSeal Hydrogel Wound Dressing
K023612– Silverlon Contact Wound Dressing

Indication for Use:
For Over-the-Counter Use:
SilverSeal Hydrogel Wound Dressing made with X-Static is indicated for the topical management of minor superficial wounds, minor lacerations, minor abrasions and minor first degree burns.

Device Description:
Hydrogel Wound Dressings with X-Static are designed to intimately contact the wound as a primary dressing and permit the passage of fluids.

Basic Scientific Concepts that form the basis for the device:
The Hydrogel Wound Dressing with X-Static permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in the dressing consist of a thin layer of metallic silver.

Significant physical and performance characteristics of the device:
Hydrogel Wound Dressings with X-Static are made of flexible sterile nonadherent hydrogel consisting of water and polymer with nylon fibers coated with metallic silver suspended in the hydrogel.

Substantial Equivalence:
Hydrogel Wound Dressing with X-Static is substantially equivalent to the device that was cleared in K040019. The purpose of this 510(k) is to seek clearance of modified labeling that clarifies Over-the-Counter uses of the previously cleared indications.

Statement of how the technological characteristics of the device compare to those of the predicate device:
The technological characteristics of the device such as flexible primary dressing, permeability to oxygen and fluids that are substantially equivalent to the predicate devices cited.

Performance Data:
Hydrogel Wound Dressing with X-Static is the same product that was cleared in K040019 as the X-Static SilverSeal Hydrogel Wound Dressing. Therefore, the performance data provided in K040019 (section 6.2 pages 12-13 of K040019) is applicable to the 510(k) and no new performance data is provided.