

**Indications for Use**

510(k) Number (if known): K113693

Device Name: Nixall™ Wound and Skin Care

**Indications For Use:**

Nixall™ Wound and Skin Care, is intended for over the counter and professional use as follows:

**OTC:** Nixall™ Wound and Skin Care is for the management of, the irrigation of, the moistening of, and lubrication of minor skin abrasions, minor lacerations, minor burns, minor irritations, minor cuts, and intact skin.

**Prescription Use:** Nixall™ Wound and Skin Care is intended to be used by health care professionals in the management, via debridement of wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Jiyoung Dang**

(Division Sign-off)  
Division of Surgical Devices  
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