

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 is for the management of, the irrigation of, the moisturizing 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 1-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over The Counter Use X
AND/OR (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
510 (k) Number K113693

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