

510 (k) SUMMARY

K965120

I. ADMINISTRATIVE

Submitter: Healthpoint Medical
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MAR 21 1997

Contact Person: John Maverick

Date of Preparation: March 20, 1997

II. DEVICE NAME

Proprietary Name: Allclenz™ Wound Cleanser

Common Name: Wound Cleanser

Classification Name: Liquid bandage

III. PREDICATE DEVICE

Dermagran Wound Cleanser with Zinc; Derma Sciences, Inc.; K945802; 2/27/95.

IV. DEVICE DESCRIPTION

The Allclenz™ Wound Cleanser is a colorless, transparent solution supplied non-sterile in 12 fl. oz. plastic bottles equipped with trigger-spray intended for cleansing and irrigation of dermal wounds.

Biocompatibility of the product has been established by primary dermal irritation (rabbit), ocular irritation (rabbit), sensitization (guinea pig), and *in vitro* cytotoxicity studies.

V. INTENDED USE

For the cleansing of dermal lesions such as stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor irritation of the skin.

VI. COMPARISON TO PREDICATE DEVICES

The Allclenz™ Wound Cleanser is similar in composition, function and intended use to the Dermagran Wound Cleanser with Zinc (Derma Sciences, Inc.) and other similar wound cleansers.

Accordingly, Healthpoint Medical concluded that the Allclenz™ Wound Cleanser is safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the Dermagran Wound Cleanser with Zinc.