510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

I. SUBMITTER

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II. DEVICE

Name of Device: Hydrocleanse Antimicrobial Skin and Wound Care Solution
Common or Usual Name: Wound Cleanser
Classification Name: Solution, Saline Wound Dressing
Regulatory Class: Unclassified, Pre-amendment status
Product Code: FRO

III. PREDICATE DEVICE

Hydrocleanse Wound Solution manufactured by Sonoma Pharmaceuticals (K141012)
Simple Science Skin and Wound Cleanser manufactured by Simple Science (K1600095)

IV. DEVICE DESCRIPTION

The Hydrocleanse Antimicrobial Skin and Wound Care Solution is a colorless, slightly chlorinated odor, clear aqueous solution for moistening of wound dressings, wound debridement, and device irrigation with a pH range of 4.0 – 5.8. The solution will be supplied in polyethylene terephthalate (PET) round-bottles with polypropylene (PP) screw-top closure and sprayer.

V. INDICATIONS FOR USE

Rx Indications for Use:
Under the supervision of a healthcare professional, Hydrocleanse™ Antimicrobial Skin and Wound Care Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown

toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC Indications for Use:
OTC Hydrocleanse™ Antimicrobial Skin and Wound Care Solution is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Submitter/ Holder	**Proposed Device: Hydrocleanse Antimicrobial Skin and Wound Care Solution Sonoma Pharmaceuticals, Inc.**	**Predicate Device: K141012 Hydrocleanse Skin and Wound Care Solution Sonoma Pharmaceuticals, Inc.**	**Predicate Device: K1600095 Simple Science Skin and Wound Cleanser Simple Science, LLC**
Indications for Use	**Rx Indications:** Under the supervision of a healthcare professional, Hydrocleanse™ Antimicrobial Skin and Wound Care Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds. **OTC Indications:** OTC Hydrocleanse™ Antimicrobial Skin and Wound Care Solution is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	**Rx Indications:** Under the supervision of a healthcare professional, Hydrocleanse ™ Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first- and second-degree bums, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended for the irrigation, moistening and lubricating of wound dressings as well as device irrigation. **OTC Indications:** Hydrocleanse ™ Solution is intended for OTC use in the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	**Rx Indications:** For management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first-and second degree burns, grafted and donor sites, and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings. **OTC Indications:** For management of minor skin abrasions, minor lacerations, minor irritations, minor cuts, minor burns and intact skin.
Sterility Claim	Non-sterile	Same	Same
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the wound or device.	Same	Same
Delivery System	Aqueous Solution	Same	Same
Shelf Life	24 months	Same	12 months

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
The biocompatibility evaluation for the Hydrocleanse Antimicrobial Skin and Wound Care Solution was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Bench Testing
The following tests were performed to support the performance of Hydrocleanse Antimicrobial Skin and Wound Care Solution: package integrity, visual inspection, osmolality, pH, Free Available Chlorine (FAC). USP <51> testing was used to support preservative effectiveness within the solution while on the shelf, used against the following bacteria in solution, Proteus mirabilis (ATCC- 25933), Serratia marcescens (ATCC-8100), antibiotic resistant Methicillin-Resistant Staphylococcus aureus (MRSA) (ATCC-43300), Vancomycin-resistant Enterococcus faecalis (VRE) (ATCC-700221), and Acinetobacter baumannii (ATCC 19606).

VIII. CONCLUSION

Hydrocleanse Antimicrobial Skin and Wound Care Solution is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Hydrocleanse Wound Solution manufactured by Sonoma Pharmaceuticals, Inc. (K141012) and Simple Science Antimicrobial Skin and Wound Cleanser manufactured by Simple Science (K1600095). Therefore, the Hydrocleanse Antimicrobial Skin and Wound Care Solution is substantially equivalent to the predicate devices.