September 12, 2019

Ascent Consumer Products, Inc.
Carey Bottom
Consulting Associate
105 Baylis Road
Melville, New York 11747

Re: K183662
Trade/Device Name: Saline Wound Wash; SteriCleanse™
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 5, 2019
Received: August 12, 2019

Dear Carey Bottom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183662

Device Name
SALINE WOUND WASH, SteriCleanse(TM)

Indications for Use *(Describe)*
To cleanse minor wounds, scrapes and minor burns

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

SALINE WOUND WASH

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared/Revised

ASCENT CONSUMER PRODUCTS, INC.
105 BAYLIS RD
MELVILLE NY 11747-3833

Phone: (631) 755-1155
Facsimile: (631) 755-1195

Contact Person: Carey Bottom
cbottom@gmail.com

Date Revised: September 12, 2019

2. Name of Device and Name/Address of Sponsor

Saline Wound Wash

ASCENT CONSUMER PRODUCTS, INC.
105 BAYLIS RD
MELVILLE NY 11747-3833

3. Common or Usual Name

Wound Cleanser; Steri*Cleanse* ™

4. Classification Name

Common or usual name:	Dressing, Wound, Drug
Classification name:	Unclassified
Product code:	FRO

5. Device Description

Saline Wound Wash is an isotonic sterile saline solution packaged in a bag-in-can (also known as bag-on-valve, BOV) aerosol system. Actuation of the valve device delivers a consistent flow of sterile isotonic saline solution at the wound site. The flow of isotonic saline solution at the wound or abrasion site aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudate and other extraneous

matter. No preservatives are added since the finished device is sterilized by gamma irradiation under parameters that have been validated according to ANSI/AAMI/ISO 11137-1:2006/(R) 2015 & A1:2013 requirements [Sterilization of Health Care Products – Requirements for development, validation and routine control of a sterilization process for medical devices]. Saline Wound Wash passes the USP<71> Sterility Test.

Saline Wound Wash is intended to be used for cleansing dermal wounds. The mechanical action of sterile isotonic saline solution irrigating the wound assists in the cleansing and removal of foreign material. Saline Wound Wash will also help remove tissue debris, wound exudate, and other extraneous matter allowing for a cleansed wound and any necessary subsequent wound dressing. It may also be used to moisten dressings to ease removal from the wound area.

6. Predicate Device

Wound Wash Saline ® [K083355]; (Currently labeled as Simply Saline™ Wound Wash)

7. Intended Use / Indications for Use

Saline Wound Wash is an over-the counter device/product and is labeled for use in cleansing wounds as follows: "To cleanse minor wounds, scrapes and minor burns".

It may also be used to moisten dressings to ease removal from the wound area.

8. Technological Characteristics

Saline Wound Wash is an aerosol bag-in-can system, otherwise also known as a bag-on-valve (BOV). The propellant, compressed air, is charged into the container between the bag and the can creating internal pressure and a means to dispense the contents (isotonic sterile saline solution) of the bag by pressing on the actuator. The bag is a 4-layer laminate system including a sandwiched aluminum layer establishing an impermeable barrier between the propellant (compressed air) and the bag contents (sterile isotonic saline). The device formulation, isotonic saline solution, is in contact with a polyethylene liner/layer. New or other suppliers of BOV systems may use polypropylene. Saline Wound Wash is a clear, colorless 0.9% sodium chloride solution prepared from Sodium Chloride, USP and Purified Water, USP. After filling and pressurizing, the device is sterilized by gamma irradiation at a contract gamma irradiation sterilizer. The validation of sterilization and subsequent testing has been carried out. The product is tested against established manufacturing specifications and meets current USP sterility requirements.

The device has been tested and conforms to the currently official (May 1, 2018) USP monograph, Sodium Chloride Irrigation.

The content volume of the Predicate Device as marketed is 7.1 FL OZ (210 mL) compared to the Ascent Device at 7.4 Fl OZ (211 g).

Comparison of Device and Predicate Device

	Saline Wound Wash [DEVICE]	Wound Wash Saline, 210 mL, Model B8552 [K083355] (Now known as Simply Saline™ Wound Wash [K083355]
OTC or Rx	OTC	OTC
Indications for Use	To cleanse minor wounds, scrapes and minor burns	To cleanse wounds, scrapes and minor burns
Ingredients /Composition	Isotonic saline solution [0.9% Sodium Chloride Solution]	Isotonic saline solution [0.9% Sodium Chloride Solution]
Drug Component	No	No
Antibacterial claims	No	No
Sterile	Yes	Yes
Packaging	7.4 oz (211g)	7.1 oz (210 mL) (originally marketed at 90 & 210 cc)
Delivery System	Bag-on-valve	Bag-on-valve

9. Substantial Equivalence

Saline Wound Wash is as safe and effective as the Predicate Device. It is very similar in all physical and performance characteristics as the Predicate Device. Saline Wound Wash has the same intended uses. It has very similar technical characteristics as well as the same basic principles of operation as the Predicate Device.

Laboratory testing of the componentry and formulation of the Predicate Device was carried out and all technological characteristics including can pressure, pH, and saline concentration are used in Saline Wound Wash. The data so obtained support technical equivalence of Saline Wound Wash and the Predicate Device. Therefore, the new device raises no issues of safety and effectiveness.

Saline Wound Wash is substantially equivalent to the Predicate Device.

This concludes the 510(k) Summary