August 17, 2018

Simple Science LLC
Eoin Croke
CTO
5555 W 78th St. STE M
Edina, Minnesota 55439

Re: K181074
Trade/Device Name: Simple Science Antimicrobial Facial and Eyelid Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 16, 2018
Received: July 17, 2018

Dear Eoin Croke:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K181074

Device Name
Simple Science Antimicrobial Facial & Eyelid Cleanser

Indications for Use *(Describe)*

• For Over-the-Counter Use: For management of minor skin abrasions, minor lacerations, minor irritations and intact skin of the face, eyelid and eyelashes.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. **Submitter's Name and Address**
   Simple Science, LLC.
   5555 W 78th St STE M
   Edina, MN 55439

2. **Submitter's Contact Person**
   Eoin Croke
   (612) 367-4540
   eoin.croke@simplesciencellc.com

3. **Date of 510(k) Summary Preparation:**
   16th August 2018

4. **Device Name (Proprietary)**
   Simple Science Antimicrobial Facial & Eyelid Cleanser

5. **Common Name**
   Wound Dressing Solution

6. **Classification Name**
   Wound Dressing, Drug

7. **Device Class**
   Unclassified

8. **Device Code**
   FRO

9. **Legally Marketed Device for substantial equivalence comparison:**
   Simple Science Antimicrobial Facial & Eyelid Cleanser is substantially equivalent to the following cleared predicate devices:

   1) Simple Science Antimicrobial Wound and Skin Cleanser (OTC and Professional use) manufactured by Simple Science LLC, cleared for distribution under 510(k) K160095 (June-10th-2016)

10. Description of Device

Simple Science Antimicrobial Facial & Eyelid Cleanser is a clear hypotonic solution topically applied to skin, eyelid and wound areas. The subject device is a wound management and cleansing solution that is intended for cleansing, irrigating, and debriding dermal wounds in addition to moistening and lubricating absorbent wound dressings (e.g. gauze). The mechanical action of fluid moving across the wound provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. Simple Science Antimicrobial Facial & Eyelid Cleanser contains the following ingredients: Ionized water (99.927%), Sodium chloride (0.06%), Hypochlorous acid (0.011%) and hypochlorite Ion (0.002%). Simple Science Antimicrobial Facial & Eyelid Cleanser will be supplied in 2 oz Glass bottle with spray inserts / caps.

11. Intended Use of Device

Simple Science Antimicrobial Facial & Eyelid Cleanser is intended for over-the-counter (OTC) use as follows:

For Over-the-Counter Use: For management of minor skin abrasions, minor lacerations, minor irritations, and intact skin of the face, eyelid and eyelashes.

These indications are similar to that of the predicate device.

12. Device Technological Characteristics

Simple Science Antimicrobial Facial & Eyelid Cleanser is a clear hypotonic solution to aid in the removal of debris and foreign material from the application site. This is accomplished through the flow of the solution moving across the application site with or without the assistance of a suitable wound dressing. Simple Science Antimicrobial Facial & Eyelid Cleanser solution contains hypochlorous acid, a known antimicrobial preservative, which is shown to inhibit the growth of microorganisms such as Candida albicans, Aspergillus brasiliensis, acinetobacter albumin, Vancomycinresistant Enterococcus (VRE), Escherichia coli, Pseudomonas aeruginosa, Staphylococcus epidermidis, and Methicillin-resistant Staphylococcus aureus (MRSA) in the liquid. Simple Science Antimicrobial Eyelid Cleanser is manufactured under Good Manufacturing Practices (GMP) guidelines

The ingredients of the solution are identical to those of the predicate. The subject device is supplied in 2 oz Glass bottle with spray inserts / caps, while the predicate device is supplied in a Polyethylene Terephthalate (PET) bottle of various sizes (from 2 OZ to 23 OZ) with spray inserts/caps.

13. Performance Testing

Simple Science Antimicrobial Facial & Eyelid Cleanser has been subjected to ISO 10993 biocompatibility studies (cytotoxicity, sensitization, irritation, ocular) to demonstrate that the device is as safe and as effective as its predicate devices. The preservative effectiveness has been supported by USP <51> testing. Additionally, Test results have demonstrated preservative effectiveness 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). The results of the stability study demonstrate that the product is stable and effective for the entire shelf life of 12Months.

14. Substantial equivalence conclusion

Simple Science Antimicrobial Facial & Eyelid Cleanser is similar in function and has the same intended use as the predicate devices Simple Science Animicrobial™ Skin and Wound Cleanser, K160095, The safety evaluation meets the requirements as detailed by USP and ISO.

On the basis of the information presented in this 510(k) submission, Simple Science, LLC. concludes a) that Simple Science Antimicrobial Facial & Eyelid Cleanser is substantially equivalent to the predicate devices, as it has the same intended use as the predicates; and b) demonstrates that the device is at least as safe and as effective as the legally marketed predicate devices.