April 23, 2021

Next Science, LLC
Courtney Narain
Regulatory Affairs Specialist
10550 Deerwood Park Blvd Ste 300
Jacksonville, Florida 32256

Re: K203835
Trade/Device Name: MIS Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 25, 2021
Received: March 26, 2021

Dear Courtney Narain:

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,

Lixin Liu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203835

Device Name
MIS Solution

Indications for Use *(Describe)*
MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms from wounds.

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.

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510(k) Summary

MIS Solution

Submitter: Next Science®, LLC
10550 Deerwood Park
Suite 300
Jacksonville, Florida 32256

Contact Person: Courtney Narain
Regulatory Affairs Specialist
855-564-2762 ext. 6004
855-564-2460 (fax)

Date Prepared: April 23, 2021

Device Trade Name: MIS Solution

Device Common Name: Wound Irrigation Solution

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

Predicate Device: Next Science® Irrigation Solution (K161165)

Indications For Use: MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.

Device Description:

MIS Solution is a clear, colorless solution intended for cleansing and removal of debris, including microorganisms, from wounds.

The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds. MIS Solution is provided in a soft polypropylene 500mL container with a spikeable port. MIS Solution is composed of water, citric acid, sodium citrate and sodium lauryl sulfate.

Technological Characteristics:

MIS Solution (subject device) and Next Science® Irrigation Solution (predicate device) consist of different ingredients. However, while the device technology is different between the subject and predicate device, the function of each ingredient is analogous. Both devices incorporate a surfactant to assist in the solubilization of debris, a buffer system to maintain the pH of the formulation and a vehicle to carry away debris from the wound.

The table below compares MIS Solution to the predicate device.

Product	MIS Solution	Next Science® Irrigation Solution (Predicate)
Company	Next Science®, LLC	Next Science®, LLC
510(k) Number	K203835	K161165
Indications	MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.	Next Science® Irrigation Solution is to be used with a jet lavage system and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.
Composition	**pH Buffer** Sodium Citrate 31.33 g/L Citric Acid 32.50 g/L	**pH Buffer** Sodium Acetate 30.00 g/L Acetic Acid 50.00 g/L
	Surfactant Sodium Lauryl Sulfate 1.00g/L	**Surfactant** Benzalkonium Chloride 1.3 g/L
	Vehicle Water	**Vehicle** Ethanol 100 g/L Water
Sterility	Sterile	Sterile
Mechanism(s) of Action	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as, microorganisms, dirt and debris. The mechanical action can be provided by either a manual syringe or powered irrigation device.	Mechanical removal of debris via hydrodynamic shear. The mechanical action of moving across the wound aids in the removal of foreign material such as dirt and debris. The mechanical action of the irrigation is provided by the Pulsavac Plus lavage systems.

Biocompatibility

The biocompatibility of MIS Solution has been evaluated in accordance with ISO 10993-1:2018 and FDA guidance "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The battery of studies includes the following:

- Material Mediated Pyrogenicity using USP <151>
- Guinea Pig Maximization Sensitization Test
- Porcine Wound Healing to address the cytotoxicity endpoint
- Toxicological Risk Assessment per ISO 10993-17
- Chemical Characterization of Extractables and Leachables for device packaging
- Irritation (Human)

Performance Bench Testing

The following bench tests were conducted to support the substantial equivalency of MIS Solution in removing debris from a surface and adequate irrigation:

- Compatibility and Irrigation Force Comparison – the test verified that use of the subject device in manual and powered irrigation devices were able to reach published pressures deemed adequate for wound irrigation.
- Combined Dissolution Efficacy – The test demonstrated that MIS Solution and the predicate device are substantially equivalent at removing debris under static conditions.

Animal Testing

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device components on the wound healing process.

In the animal study conducted, 16 domestic pigs were used, each receiving eight wounds, four on the left and right sides of the animal's back parallel to the spine line. Two or three of the animal's wounds were assigned to a treatment group of the subject device, the predicate device or a negative control.

Under the conditions of the study, MIS Solution did not inhibit normal wound healing over 25 days in this porcine wound healing study.

Clinical Study

MIS Solution was evaluated in a Human Repeat Patch Test to evaluate the irritation endpoint in humans. MIS Solution was determined to be a non-irritant. There were no adverse events or complications in this study.

Conclusion:

The conclusions drawn from biocompatibility, performance tests and a clinical study demonstrate that MIS Solution is as safe and effective as the legally marketed device, Next Science® Irrigation Solution (K161165).