September 23, 2021

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

Re: K203446
Trade/Device Name: TorrentX Wound Wash
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 19, 2021
Received: August 20, 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)*

K203446

Device Name

TorrentX Wound Wash

Indications for Use *(Describe)*

TorrentX Wound Wash 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

TorrentX Wound Wash

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: September 21, 2021

Device Common Name: Wound Wash

Device Trade Name: TorrentX Wound Wash

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Classification: Unclassified

Predicate Device: Next Science® Irrigation Solution (K161165)

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

Device Description:

TorrentX Wound Wash is a non-sterile, clear, colorless, aqueous solution that is used to remove 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 foreign material such as debris and bacteria via hydrodynamic shear.

TorrentX Wound Wash will be provided in a 20mL low density polyethylene ampoule with a twist-off seal. Ten (10) ampoules and applicator tips will be provided together in a shelf carton.

The formulation for TorrentX Wound Wash is composed of ethanol, water, sodium citrate, citric acid and benzalkonium chloride.

Technological Characteristics:

TorrentX Wound Wash contains ethanol, water, citric acid, sodium citrate and benzalkonium chloride. All the components of TorrentX Wound Wash are consistent with known ingredients for cleared wound dressings under the FRO product code.

TorrentX Wound Wash and Next Science® Irrigation Solution are both clear, colorless solutions used for cleansing wounds. Both devices share the same mechanism of action and use in a clinical setting. The proposed and predicate devices contain the same surfactant to assist in the solubilization of debris and the same vehicle to carry away any debris that is washed from the wound during the irrigation process. As shown by the bench, animal and biocompatibility testing, the difference in ingredients do not raise different questions of safety or effectiveness. The following table compares TorrentX Wound Wash to the predicate device.

Product	Torrent X Wound Wash (Proposed)	Next Science® Irrigation Solution (Predicate)
Company	Next Science, LLC	Next Science, LLC
510(k) Number	K203446	K161165
Indications	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	Benzalkonium Chloride Ethanol Citric Acid Sodium Citrate Water	Benzalkonium chloride Ethanol Acetic acid Sodium acetate Water
Target Population	Single patient use	Single patient use
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.	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 AC lavage system.
Sterility	Non-sterile	Sterile
Instructions	Not for repeated use One ampoule per procedure	Not for repeated use

Summary of Nonclinical Studies

The following tests were performed to support the safety, effectiveness and substantial equivalency of TorrentX Wound Wash:

Performance Bench Testing

- Application Pressure Test
- Antimicrobial Effectiveness Test (Preservation) (USP <51>)
- Endotoxin LAL Test

Animal Testing

- Porcine Wound Healing Study

Biocompatibility Testing

- Sensitization
- Material-mediated Pyrogenicity
- Toxicological Risk Assessment

Conclusion:

The conclusions drawn from the performance tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device Next Science® Irrigation Solution (K161165).