January 23, 2020

Next Science, LLC
Jeanne Lee
Regulatory Manager
10550 Deerwood Park Blvd., Ste. 300
Jacksonville, Florida 32256

Re: K192349
Trade/Device Name: Bactisure Wound Lavage
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH
Dated: November 22, 2019
Received: November 26, 2019

Dear Jeanne Lee:

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,

For Kimberly Ferlin, 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192349

Device Name
Bactisure Wound Lavage

Indications for Use *(Describe)*
Bactisure Wound Lavage is to be used with the Zimmer Pulsavac Plus or Pulsavac Plus AC lavage systems and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.

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

[x] 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.***

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# K192349 510(k) Summary

# Bactisure™ Wound Lavage


| | |
|---|---|
| Applicant: | Next Science™, LLC<br>10550 Deerwood Park<br>Suite 300<br>Jacksonville, FL 32256 |
| Contact Person: | Jeanne Lee<br>Next Science™, LLC<br>10550 Deerwood Park<br>Suite 300<br>Jacksonville, FL 32256<br>Regulatory Affairs Manager<br>1-855-564-2762 ext. 6003 |


| | |
|---|---|
| Date Prepared: | August 26, 2019 |
| Device Trade Name: | Bactisure™ Wound Lavage |
| Device Common Name: | Jet Lavage |
| Classification Name: | Lavage, Jet |
| Product Code: | FQH, FRO |
| Classification: | Class II, unclassified |
| CFR: | 21 CFR 880.5475 |

**Predicate Device:**
Next Science™ Irrigation Solution, K161165

**Indications for Use:**
Bactisure Wound Lavage is to be used with the Zimmer Pulsavac Plus or Pulsavac Plus AC lavage systems and is indicated for use in cleansing and removal of debris, including micro-organisms, from wounds.

**Device Description:**
Bactisure Wound Lavage is an aqueous solution for irrigation and debridement of wounds. The solution is a clear, colorless, low-odor 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 debris, including microorganisms, from wounds.
Bactisure Wound Lavage is provided in a 1000mL polypropylene plastic container with a single port and will be labeled “not for IV use”. The container will be provided in a

polyethylene overwrap and packaged. The formulation for Bactisure Wound Lavage is composed of ethanol, acetic acid, sodium acetate, benzalkonium chloride, and water.

**Technological Characteristics:**
The table below summarizes any technological characteristics of Bactisure Wound Lavage as compared to the predicate device Next Science Irrigation Solution, K161165.

| | **Bactisure™ Wound Lavage** | **Next Science™ Irrigation Solution (Cleared Device K161165)** |
|---|---|---|
| **Indication for use** | Bactisure Wound Lavage is to be used with the Zimmer Pulsavac Plus or Pulsavac Plus AC lavage systems and is indicated for use in cleansing and removal of debris, including micro-organisms, 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 microorganisms, from wounds. |
| **Mechanism(s) of Action** | Mechanical removal of debris via hydrodynamic shear.<br>The mechanical action of moving across the wound aids in the removal of foreign material such as dirt and debris. | |
| **Description** | Clear, colorless, low-odor solution containing ethanol, acetic acid, sodium acetate and benzalkonium chloride. | |
| **Composition** | Ethanol, 100g/L<br>Acetic acid, 59g/L<br>Sodium acetate, 30g/L<br>Benzalkonium chloride, 1.3g/L<br>Purified water | Ethanol, 100g/L<br>Acetic acid, 50g/L<br>Sodium acetate, 30g/L<br>Benzalkonium chloride, 1.3g/L<br>Purified water |

**Performance Testing:**
Biocompatibility testing meets the requirements of ISO 10993-1.
Sterilization meets the requirements of ISO 11737-2, ISO 14937 and ISO 17665-1.
The addition of the contraindication "Due to the ethanol content, do not use this product on neonates or infants (children under the age of 2)" and update to the warnings within the instructions for use are supported by literature and risk analyses.
Biocompatibility concerns related to the change in composition were mitigated by a toxicological risk analysis.

**Conclusion:**
The conclusions drawn from the performance tests demonstrate that the device is as safe and effective as the legally marketed device Next Science Irrigation Solution (K161165).