DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 7, 2016

Next Science, LLC
Matthew Myntti, Ph.D.
President
8130 Baymeadows Way West, Suite 200
Jacksonville, FL 33256

Re: K161165
Trade/Device Name: Next Science Irrigation Solution
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: Class II
Product Code: FQH
Dated: August 9, 2016
Received: August 9, 2016

Dear Dr. Myntti:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161165

Device Name
Next Science Irrigation Solution

Indications for Use *(Describe)*
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.

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: K161165

Next Science™ Irrigation Solution

Submitter:	Next Science™, LLC 8130 Baymeadows Way West Suite 200 Jacksonville, Florida 32256
Contact Person:	Matthew Myntti, Ph.D. President, Next Science™, LLC 855-564-2762 ext. 1004
Date Prepared:	September 2, 2016
Device Trade Name:	Next Science™ Irrigation Solution
Device Common Name:	Irrigation Solution
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO and FQH
Classification:	Unclassified
Predicate Device:	Prontosan Wound Irrigation Solution (K072876)
Reference Device:	Atteris Antimicrobial Skin & Wound Cleanser (K160192). This device is referenced because, like the proposed device, it is intended for cleansing and removal of debris, including microorganisms, from wounds.
Device Description:	Next Science™ Irrigation Solution 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. Next Science™ Irrigation Solution will be provided in a 1000 mL 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 with six (6) containers per case.
The formulation for Next Science™ Irrigation Solution is composed of ethanol, acetic acid, sodium acetate, benzalkonium chloride and water.

Indications For Use: 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.

Substantial Equivalence: The proposed device and the predicate device are intended for use in the irrigation of wounds. Although the proposed device and the predicate device consist of different ingredients, these differences do not raise different questions of safety or effectiveness. The safety and effectiveness of the Next Science™ Irrigation Solution is supported by biocompatibility testing, functional performance testing, animal testing, and shelf-life testing conducted on the proposed device.

Product	**Next Science™ Irrigation Solution**	**Prontosan Wound Irrigation Solution (K072876)**
Company	Next Science, LLC	B. Braun
510(k) Number	K161165	K072876
Classification	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FRO, Dressing, Wound, Drug
Composition	Ethanol, 100g/L Acetic acid, 50g/L Sodium acetate, 30g/L Benzalkonium chloride, 1.3g/L Purified water	0.1% Undecylenamidopropyl betaine 0.1% Polyaminopropyl biguanide Sodium hydroxide Purified water
Description	Next Science™ Irrigation Solution is a clear, colorless liquid containing ethanol, acetic acid, sodium acetate,	Prontosan Wound Irrigation Solution is a clear, colorless liquid containing undecylenamidopropyl betaine,

Product	Next Science™ Irrigation Solution	Prontosan Wound Irrigation Solution (K072876)
	and benzalkonium chloride.	polyaminopropyl biguanide, sodium hydroxide and purified water.
Indications	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.	Prontosan Wound Irrigation Solution is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.
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 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.

Performance testing:

Next Science™ Irrigation Solution is categorized as a surface device with limited contact per ISO10993-1:2007, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and FDA’s Draft Guidance for Industry and Food and Drug Administration Staff “Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” (April 23, 2013).

Biocompatibility testing was conducted in accordance with International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA, and included the following:

- ISO Intracutaneous Reactivity Test to determine if the solution was capable of causing local dermal irritation.
- ISO Guinea Pig Maximization Sensitization Test (GLP - Method for Liquid Test Article) to evaluate the solution’s allergenic potential or sensitizing capacity.

Animal testing:

A Porcine Dermal Full-Thickness Wound Wash Study was conducted to evaluate the effect of the Irrigation Solution components on the wound healing process.

In the animal study conducted, eight Yorkshire pigs were used each receiving eight wounds, four on either side of the dorsal midline. The four wounds were treated with the same control or test solution, or an empty control (no treatment). The empty control article was included to serve as a baseline.

Under the conditions of the porcine wound healing study, Next Science Irrigation Solution resulted in normal wound healing and was comparable to wounds that received the control article and wounds without treatment over 24 days in this porcine full-thickness dermal wound model.

Substantial Equivalence Conclusions:

The Indications for Use statement for Next Science™ Irrigation Solution is similar to that for the predicate device, and the differences in ingredients do not raise different questions of safety or effectiveness. The performance testing and animal testing demonstrate that Next Science™ Irrigation Solution is at least as safe and effective as the predicate device. Therefore, the information in this submission demonstrates that Next Science™ Irrigation Solution is substantially equivalent to the predicate device.