DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 6, 2017

Next Science, LLC
Matthew Myntti, Ph.D.
President
8130 Baymeadows Way W, Suite 200
Jacksonville, Florida 32256

Re: K163188
Trade/Device Name: Next Science Wound Gel (Rx)
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 10, 2017
Received: February 10, 2017

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" (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 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,

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)*

Device Name
Next Science Wound Gel (Rx)

Indications for Use *(Describe)*
Next Science Wound Gel (Rx) is indicated for the management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

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.

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510(k) Summary
K163188

Next Science™ Wound Gel (Rx)

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:	February 8, 2017
Device Trade Name:	Next Science™ Wound Gel (Rx)
Device Common Name:	Wound Dressing
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Classification:	Unclassified
Predicate Devices:	Anasept Antimicrobial Skin and Wound Gel (K073547) (primary predicate) Next Science Wound Gel (K150792)
Device Description:	Next Science Wound Gel is a hydrogel that helps to maintain a moist wound environment that is conducive to healing. The antimicrobial agent, benzalkonium chloride, inhibits the growth of microorganisms in the hydrogel. The Wound Gel is applied directly to the wound and then covered with an appropriate dressing. The use of the hydrogel on a wound creates a moist environment that is conducive to healing by either absorbing wound exudate or donating moisture. The Wound Gel will be supplied in both 1 ounce and 4-ounce low-density polyethylene tubes with a screw-

top opening. Lot number and expiration dating will be embossed on the printed tube.

Intended Use: Next Science™ Wound Gel is intended for use in the management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

Substantial Equivalence: The proposed device has the same indications for use as the predicate device, Anasept Antimicrobial Skin and Wound Gel, and the same technological characteristics as the predicate device, Next Science Wound Gel (OTC), as shown in the following table. The safety and effectiveness of the Next Science™ Wound Gel (Rx) is supported by biocompatibility, functional performance, and shelf-life testing.

Product/ 510k #	**Next Science Wound Gel™(Rx) K163188**	**Next Science Wound Gel™ (OTC) K150792**	**Anasept Antimicrobial Skin and Wound Gel K073547**
Company	Next Science™, LLC	Next Science™, LLC	Anacapa Technologies
Composition	Benzalkonium chloride 0.13%, polyethylene glycol 400, polyethylene glycol 3350, sodium citrate, citric acid and water	Benzalkonium chloride 0.13%, polyethylene glycol 400, polyethylene glycol 3350, sodium citrate, citric acid and water	Isotonic hydrogel and antimicrobial sodium hypochlorite and water
Product Code	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)
Product Description and Characteristics	A hydrogel that helps to maintain a moist wound environment that is conducive to healing. The antimicrobial agent, benzalkonium chloride, inhibits the growth of microorganisms in the hydrogel.	A hydrogel that helps to maintain a moist wound environment that is conducive to healing. The antimicrobial agent, benzalkonium chloride, inhibit the growth of microorganisms in the hydrogel.	A hydrogel that helps maintain a moist wound environment that is conducive to healing. The antimicrobial agent inhibits the growth of bacteria such as: *Staphlyococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Proteus mirabilis, Serratia marcescens, Acinetobacter baumannii*, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), and Vancomycin resistant *Enterococcusfaecalis* (VRE) that are commonly found in the wound bed,

Product/ 510k #	Next Science Wound Gel™(Rx) K163188	Next Science Wound Gel™ (OTC) K150792	Anasept Antimicrobial Skin and Wound Gel K073547
			as well as, fungi such as *Candida albicans* and *Aspergillus niger.*
Indications	Rx: Management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.	OTC: Management of skin abrasions, lacerations, minor irritations, cuts, exit sites, and intact skin.	Rx: Management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. OTC: Management of skin abrasions and lacerations, minor irritations, cuts, exit sites and intact skin.
Mechanism of Action	Provides a moist wound environment that is conducive to healing.	Provides a moist wound environment that is conducive to healing.	Provides a moist wound environment that is conducive to healing.

Performance Testing:

Next Science™ Wound Gel (Rx) has been subjected to biocompatibility studies to demonstrate that the device is safe for the indicated use. These biocompatibility studies demonstrated that Next Science™ Wound Gel is compliant with the requirements of ISO 10993.

The gel's ability to aid in the management of wounds has been demonstrated by a full thickness wound study. Preservative efficacy has been demonstrated through USP Antimicrobial Effectiveness Testing <51> and <61> to demonstrate that the Wound Gel will not introduce bacteria to the application site.

Substantial Equivalence Conclusions:

The Indications for Use and technological characteristics for Next Science™ Wound Gel (Rx) are identical to the predicate devices. The performance testing demonstrates that Next Science™ Wound Gel (Rx) is at least as safe and effective as the predicate devices. Therefore, the information in this submission demonstrates that Next Science™ Wound Gel is substantially equivalent to the predicate devices.