April 21, 2025

Spectrum Antimicrobials, Inc.
% Andrew Bosco
Vice President -Technical Regulatory Affairs
Dunn Regulatory Associates, LLC
8609 Westwood Center Drive
Suite 110
Vienna, Virginia 22182

Re: K243875
Trade/Device Name: Spectricept Skin and Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 17, 2025
Received: January 21, 2025

Dear Andrew Bosco:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243875

Device Name

Spectricept Skin and Wound Cleanser

Indications for Use *(Describe)*

Spectricept Skin and Wound Cleanser for Professional Use:
Under the supervision of a healthcare professional, Spectricept Skin and Wound Cleanser is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from wounds, and dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, superficial second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites.

Spectricept Skin and Wound Cleanser for OTC Use:
Spectricept Skin and Wound Cleanser is intended for OTC use for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from of skin abrasions, lacerations, minor irritations, cuts and intact skin.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. 510(k) Summary 510(k) Submitter & Submitter's Address

Spectrum Antimicrobials, Inc.
1770 Corporate Circle
Petaluma, CA
94954 USA

2. Submitter's Contact Information

Hoji Alimi, CEO
Phone: (707) 206-5326
Email: halimi@spectrumantimicrobials.com

3. Date and Type of 510(k) Submitted

Traditional 510(k)

January 17, 2025

4. Device Identification

Trade/Proprietary Name:	Spectricept Skin and Wound Cleanser
Common/Usual Name:	Wound Cleanser
Classification Name:	Dressing, Wound
Regulation Number:	Unclassified
Product Code:	FRO
Wound Dressing Class:	Unclassified
Classification Panel:	Surgical and Infection Control Devices (OHT4) Plastic and Reconstructive Surgery Devices (DHT4B)

5. Legally Marketed Predicate Device(s)

Device name:	Spectricept Skin and Wound Cleanser
510(k) number:	K213514
Manufacturer:	Spectrum Antimicrobials, Inc, Petaluma, CA 94954

6. Indication for Use Statements

Spectricept Skin and Wound Cleanser for Professional Use:
Under the supervision of a healthcare professional, Spectricept Skin and Wound Cleanser is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from wounds, and dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, superficial second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites.

Spectricept Skin and Wound Cleanser for OTC Use:
Spectricept Skin and Wound Cleanser is intended for OTC use for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from of skin abrasions, lacerations, minor irritations, cuts and intact skin.

7. Device Description

Spectricept Skin and Wound Cleanser is a clear hypotonic solution that aids in the removal of debris and foreign material from the application site. Foreign material and debris are mechanically removed by the action of the wound cleanser moving across the wound bed with or without the assistance of a suitable wound dressing (e.g., gauze).

Spectricept Skin and Wound Cleanser is a combination device that contains water (99.94%), hypochlorous acid, (0.036%), copper chloride (0.008%), zinc chloride (0.008%) and ferric chloride (0.008%). Hypochlorous acid functions as a preservative while the three inactive chloride salts function to assist in stabilizing hypochlorous acid in the bottle in the event that the solution is contaminated with inanimate during the device handling, operation of the spray nozzle and re-use.

Spectricept Skin and Wound Cleanser is a non-sterile aqueous solution in a 8oz PET bottle.

8. Substantial Equivalence Discussion

The following table compares the subject Spectricept Skin and Wound Cleanser to the selected predicated device. The comparisons include the following attributes which forms the basis for determining substantial equivalence:

- Indications for use,
- Technological characteristics
- Device performance.

Table 1: Comparison of Characteristics

Attribute	**Spectricept Skin and Wound Cleanser**	**Spectricept Skin and Wound Cleanser (Predicate K213514)**	**Comparison**
Manufacturer	Spectrum Antimicrobials	Spectrum Antimicrobials	n/a
Product Code	FRO	FRO	Identical
Regulation Number	Unclassified	Unclassified	Identical
Device Description	Spectricept Skin and Wound Cleanser is a clear hypotonic solution that aids in the removal of debris and foreign material from the application site. Spectricept Skin and Wound Cleanser is a combination device that contains water (99.94%), hypochlorous acid, (0.036%), copper chloride (0.008%), zinc chloride (0.008%) and ferric chloride (0.008%). Hypochlorous acid functions as a preservative while the three inactive chloride salts function to assist in stabilizing hypochlorous acid in the bottle in the event that the solution is contaminated with inanimate during the device handling, operation of the spray nozzle and re-use. Spectricept Skin and Wound Cleanser is a non-sterile aqueous solution in a 8oz PET bottle.	Spectricept Skin and Wound Cleanser is a clear hypotonic solution that aids in the removal of debris and foreign material from the application site. Spectricept Skin and Wound Cleanser is a combination device that contains water (99.94%), hypochlorous acid, (0.036%), copper chloride (0.008%), zinc chloride (0.008%) and ferric chloride (0.008%). Hypochlorous acid functions as a preservative while the three inactive chloride salts function to assist in stabilizing hypochlorous acid in the bottle in the event that the solution is contaminated with inanimate during the device handling, operation of the spray nozzle and re-use. Spectricept Skin and Wound Cleanser is a non-sterile aqueous solution in a 8oz PET bottle.	Identical
Mechanism of Action	Mechanical removal of dirt, debris from wounds by the action of fluid moving across the wound.	Mechanical removal of dirt, debris from wounds by the action of fluid moving across the wound.	Identical
Sterile	No	No	Identical

Attribute	Spectricept Skin and Wound Cleanser	Spectricept Skin and Wound Cleanser (Predicate K213514)	Comparison
Indications For Use Rx Label:	Under the supervision of a healthcare professional, Spectricept Skin and Wound Cleanser is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from wounds, and dermal lesions including stage I-IV pressure ulcers, statis ulcers, diabetic ulcers, post-surgical wounds, superficial second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafter/donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings.	Under the supervision of a healthcare professional, Spectricept Skin and Wound Cleanser is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from wounds, and dermal lesions including stage I-IV pressure ulcers, statis ulcers, diabetic ulcers, post-surgical wounds, superficial second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafter/donor sites and exit sites.	Identical
Indications For Use OTC Label	Spectricept Skin and Wound Cleanser is intended for OTC use for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from of skin abrasions, lacerations, minor irritations, cuts and intact skin.	Spectricept Skin and Wound Cleanser is intended for OTC use for cleansing, irrigating, moistening, debridement and removal of foreign material including debris from of skin abrasions, lacerations, minor irritations, cuts and intact skin.	Identical
Formulation	Water (99.94%), Hypochlorous Acid (0.036%), Copper Chloride (0.008%), Zinc Chloride (0.008%), Ferric Chloride (0.008%)	Water (99.94%), Hypochlorous Acid (0.036%), Copper Chloride (0.008%), Zinc Chloride (0.008%), Ferric Chloride (0.008%)	Identical
Single Use	No	No	Identical
Shelf Life	12 months	12 months	Identical
Container Closure System	Aqueous Solution in 8 oz PET bottles	Aqueous Solution in 8 oz PET bottles	Identical
Antimicrobial Effectiveness Testing	USP<51> - Product demonstrated acceptable performance.	USP<51> - Product demonstrated acceptable performance.	Identical

The technological characteristics of the subject device are identical to those of the predicate device. The only change has been to the label to change the device from a limited contact (<24 hours) to prolonged contact (>24 but <30 days) based on additional biocompatibility testing.

The composition of the subject device (including the size of the container closure), its indication for use, and the shelf-life of the subject device are identical to the predicate.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Spectricept Skin and Wound Cleanser and to show substantial equivalence to the predicate devices, Spectrum Antimicrobials completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device have successfully been met.

Spectricept Skin and Wound Cleanser passed the tests conducted, supporting substantial equivalence to the predicate device with respect to safety and effectiveness.

Biocompatibility Testing

The biocompatibility evaluation for the Spectricept Skin and Wound Cleanser was conducted in accordance with the FDA guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" September 4, 2020, and International Standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Biocompatibility testing was leveraged from the predicate device as the devices are the same, and that testing included the following:

- ISO 10993-3 – Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-5 – In Vitro Cytotoxicity
- ISO 10993-10 – Irritation and Skin Sensitization, Direct Intracutaneous Injection Test
- ASTM F756 – Assessment of Hemolytic Properties
- USP<85> – Bacterial Endotoxins Test
- USP <51> – Antimicrobial Effectiveness Testing

The solution is considered a breached/compromised surface device with prolonged contact (>24 hours to 30 day).

The following testing was completed:

- ISO 10993-6 – Part 6: Tests for local effects after implantation
- ISO 10993-11 – Systemic Toxicity, Direct Systemic Injection Test

The Spectricept Skin and Wound Cleanser meets specification, biocompatibility and performance characteristics and is substantially equivalent to the predicate device.

10. Clinical Performance Data

No clinical testing was conducted on Spectricept Skin and Wound Cleanser, which is consistent with the predicate devices.

11. Conclusion and Statement of Substantial Equivalence

Spectrum Antimicrobials Spectricept Skin and Wound Cleanser has the same intended uses, the same indications for use, the same mechanism of action and the same technological characteristics, and does not raise any new questions of safety or effectiveness; therefore, Spectricept Skin and Wound Cleanser is substantially equivalent to the predicate device.