January 13, 2023

Spectrum Antimicrobials, Inc. (Subsidiary of Collidion, Inc.)
% Dana Dunn
Principal
Dunn Regulatory Associates, LLC
2709 Silkwood Court
Oakton, Virginia 22124

Re: K213514
Trade/Device Name: Spectricept Skin and Wound Cleanser
Regulatory Class: Not classified
Product Code: FRO
Dated: October 29, 2021
Received: November 2, 2021

Dear Dana Dunn:

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,

Julie A. Morabito -S

Julie A. Morabito, Ph.D.
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)*
K213514

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.

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510(k) Summary

Spectricept Skin and Wound Cleanser

K213514

1. 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

April 27, 2022

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 – Solution, Saline
Wound Dressing Class:	Unclassified
Classification Panel:	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)

5. Legally Marketed Predicate Device(s)

Device name:	Microcyn Plus Wound Care Solution
510(k) number:	K161034
Manufacturer:	Oculus Innovative Sciences, Petaluma, CA 94954

6. Reference Device(s)

Device Name:	Vashe Wound Solution
510(k) number:	K131848
Manufacturer:	PuriCore Inc., Malvern, PA 19355
Device name:	NAWAlution Skin and Wound Cleanser
510(k) number:	K141660
Manufacturer:	NAWA Heilmittel GMBH, Washington, DC 20005

7. 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.

8. 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.

9. Substantial Equivalence Discussion

The following table compares the subject Spectricept Skin and Wound Cleanser to the selected predicated device and reference devices. 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	Microcyn Plus Wound Care Solution (K161034)	Comparison
Manufacturer	Spectrum Antimicrobials	Oculus Innovative Sciences	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 with a pH range for 3.0-4.3. 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). The solution will be supplied in sealed 8oz PET bottles.	The Oculus Microcyn Plus Wound Care Solution is a colorless, slightly chlorinated odor, clear aqueous solution for moistening of wound dressings, wound debridement, and use with devices intended for wound irrigation with a pH range of 3.5 – 6.0. The solution will be supplied in 40mL glass vials with Teflon lined closures.	Essentially the same. Spectricept has a slightly lower pH limit (3.0) compared to the predicate device (3.5)
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
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, 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.	Under the supervision of a healthcare professional, Microcyn Plus Wound Care Solution is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material including microorganisms and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second-degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toenails, grafted/donor sites and exit sites. It is also intended for use to moisten and	Identical

Attribute	Spectricept Skin and Wound Cleanser	Microcyn Plus Wound Care Solution (K161034)	Comparison
		lubricate wound dressings and for use with devices intended to irrigate wounds.	
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 skin abrasions, lacerations, minor irritations, cuts and intact skin.	Microcyn Plus Wound Care Solution is intended for OTC use in the management 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, Sodium Chloride, Hypochlorous acid and Sodium Hypochlorite	Both use HOCl as their main preservative. Spectrum's salts and Microcyn's hypochlorite have each passed Biocompatibility testing.
Single Use	No	No	Identical
Shelf Life	12 months	24 months	Not Equivalent
Container Closure System	Aqueous Solution in 8 oz PET bottles	Aqueous Solution in 40 mL glass vials	Microcyn is also available in additional sizes. Both devices are available in 8 oz. aqueous solution.
Preservative Effectiveness Testing	USP<51> - Product demonstrated acceptable performance.	USP <51> - Product demonstrated acceptable performance.	Identical

10. 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.

The solution is considered a breached/compromised surface device with limited contact.

The following testing was completed:

- 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
- ISO 10993-11 – Systemic Toxicity, Direct Systemic Injection Test
- ASTM F756 – Assessment of Hemolytic Properties
- USP<85> – Bacterial Endotoxins Test

Bench Testing
The following tests were performed to support the performance of Spectricept Skin and Wound Cleanser:

- Visual Inspection
- Package Integrity
- Shelf-life Testing
- pH
- Free Available Chlorine (FAC)
- Fill Volume
- Time to Kill Assay (ASTM E2315),
- Preservative Effectiveness Testing (USP <51>)
- Bioburden (USP<61>)

The Spectricept Skin and Wound Cleanser meets specification, biocompatibility and performance characteristics and is substantially equivalent to the predicate device, with the exception of shelf-life testing which only supports a 12-month shelf life.

11. Clinical Performance Data

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

12. Conclusion and Statement of Substantial Equivalence

Spectrum Antimicrobials Spectricept Skin and Wound Cleanser has the same intended uses, similar indications for use, the same mechanism of action and similar 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.