June 24, 2026

Silverceuticals, Inc.
Cameron Moeller
Coo
1396 W 200 S, Suite 2c
Lindon, Utah 84042

Re: K251929
Trade/Device Name: SilverCeuticals® Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 26, 2026
Received: May 27, 2026

Dear Cameron Moeller:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K251929

Device Name
SilverCeuticals® Antimicrobial Wound Gel

Indications for Use *(Describe)*
The device is indicated for the OTC local management of: minor burns, minor lacerations, minor abrasions, minor cuts,

It is prescription indicated by healthcare practitioner for the management of: wounds such as 1st and partial-thickness 2nd degree burns, stasis ulcers, pressure ulcers, diabetic ulcers, device insertion site wounds, surgical incision sites, graft sites, donor sites, and skin tears.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. SUBMITTER/OWNER

SILVERCEUTICALS, INC.
1396 W. 200 S. Suite 2C
LINDON, UT 84042

Phone: 385-212-4044

Contact Person: Dr. Cameron Moeller, Chief Operations Officer

Email: cam@silverceuticals.com

Date Prepared: June 27, 2025

2. DEVICE

Name of Device: SilverCeuticals® Antimicrobial Wound Gel
Name of Rx: SilverCeuticals® Antimicrobial Wound Gel Rx
Common Name: Silver Wound Gel
Classification Name: Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO

3. PREDICATE / REFERENCE DEVICES

1) 510(k) number: K211123 (Predicate Device)
   - Product Name: LUOFUCON Silver Wound Gel
   - Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
2) 510(k) number: K140483 (Reference Device)
   - Product Name: ASAP OTC Wound Dressing Gel
   - Manufacturer: ABL Medical, LLC

4. DEVICE DESCRIPTION

SilverCeuticals® Antimicrobial Wound Gel / SilverCeuticals® Antimicrobial Wound Gel Rx is a non-sterile water-based gel wound dressing that contains silver, that in laboratory tests has been shown to inhibit the growth of microorganisms within the dressing, within the container, during shelf-life.

The high moisture content gel contains a base matrix composed of inert hydrophilic and inert buffering compounds, and contains 32 ppm silver. The device is

supplied in a PP gel pump, though it may be available in other sizes and containers. The pump is contained in a cardboard box with product insert when necessitated.

5. TECHNOLOGICAL CHARACTERISTICS

SilverCeuticals® Antimicrobial Wound Gel / SilverCeuticals® Antimicrobial Wound Gel Rx is similar to the predicate devices listed above in that silver is the antimicrobial ingredient and moisture is managed using an inert aqueous base combined with a proper blend of hydrophilic substances. This device contains silver that may inhibit the growth of microorganisms within the dressing, within the container, during shelf-life. The product was evaluated through standard biocompatibility tests (ISO 10993). USP <51> testing was conducted to support 'preservative effectiveness'.

The composition of the subject device is similar to that of the primary predicate device K211123 in that they both utilize silver as the active and Carbopol as a gelling agent. The difference between the subject device and this predicate device are 1) that the subject device contains a different blend of hydrophilic agents/ingredients and 2) that the predicate uses ionic silver which is a smaller form of silver than nano-silver of the subject device.

The composition of the subject device is similar to that of the ASAP OTC Wound Dressing Gel cleared in K140483. The only difference between the subject device and the predicate device is that the subject device contains 32ppm nano-silver and the predicate device contains 24ppm nano-silver. The remaining ingredients and formulation are identical.

6. INDICATIONS FOR USE

OTC:
SilverCeuticals® Antimicrobial Wound Gel is indicated for the topical management of: minor burns, minor lacerations, minor abrasions, and minor cuts.

Prescription:
SilverCeuticals® Antimicrobial Wound Gel Rx is indicated by healthcare practitioner for the management of: wounds such as 1st and partial-thickness 2nd degree burns, stasis ulcers, pressure ulcers, diabetic ulcers, device insertion site wounds, surgical incision sites, graft sites, donor sites, and skin tears.

Intended for external use only as a single patient reusable product.

MR unsafe.

7. BIOCOMPATIBILITY TESTING

The subject device has been tested for in-vitro cytotoxicity, dermal irritation, sensitization, acute systemic toxicity, pyrogenicity, porcine wound healing study, chemical characterization, and Toxicological Risk Assessment in accordance with ISO 10993 (Biological Evaluation of Medical Devices).

8. PERFORMANCE

The preservative effectiveness of the device has been demonstrated in triplicate by 28 days antimicrobial preservative challenge tests in accordance with USP Chapter 51 guidelines and organisms.

9. CONCLUSIONS

Based on the indications for use, biocompatibility, in-vivo studies, and performance data, the SilverCeuticals® Antimicrobial Wound Gel / SilverCeuticals® Antimicrobial Wound Gel Rx is substantially equivalent to the Predicate Devices.