



January 23, 2026

Silk Holdings, Inc.
Rebecca Lacouture
President
117 Kendrick St. #700
Needham, Massachusetts 02494

Re: K252568
Trade/Device Name: New Day Skin Spray
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 22, 2025
Received: December 22, 2025

Dear Rebecca Lacouture:

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,

Yu-chieh Chiu -S

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

Indications for Use

510(k) Number (if known)
K252568

Device Name
New Day Skin Spray

Indications for Use (Describe)

New Day Skin Spray is a skin emulsion indicated for the management of dryness of skin, and atopic dermatitis. New Day Skin Spray maintains a moist skin and wound environment beneficial to the healing process.

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

AS REQUIRED BY 21 CFR 807.92

1. Contact Details

Sponsor: Silk Holdings, Inc.
117 Kendrick St. #700
Needham, MA 02494

Correspondent: Rebecca Lacouture, President & COO
117 Kendrick St. #700
Needham, MA 02494
rebecca.lacouture@evolvedbynature.com

Preparation Date: January 23, 2026

2. Device

Device Trade Name: New Day Skin Spray
Common Name: Wound spray
Classification Name: Dressing, Wound, Drug
Device Class: Unclassified (Pre-Amendment)
Product Code: FRO

3. Legally Marketed Predicate Device

Primary Predicate: EpiCeram Skin Barrier Emulsion (K052643)

4. Device Description Summary

The New Day Skin Spray is a skin emulsion designed to manage atopic dermatitis. A thin layer is to be applied to the affected area for up to 28 days or until symptoms subside. The applied thin layer of New Day Skin Spray forms a breathable layer by maintaining a moist wound and skin environment, which is beneficial to the healing process.

5. Intended Use/Indications for Use

New Day Skin Spray is a skin emulsion indicated for the management of dryness of skin, and atopic dermatitis. New Day Skin Spray maintains a moist skin and wound environment beneficial to the healing process.

6. Comparison of Technological Characteristics

The following table, Table 1: Summary Of Comparison To Predicate Devices, compares the New Day Skin Spray to the predicate device with respect to intended use, technological characteristics and principles of operation. It provides detailed information to support the determination of substantial equivalence.

TABLE 1: SUMMARY OF COMPARISON TO PREDICATE DEVICES

Description	Subject Device New Day Skin Spray Silk Holdings, Inc.	Primary Predicate Device EpiCeram Skin Barrier Emulsion (K052643) Cergnix Corporation	Comparison to Predicates and/or justification of difference not raising any new questions of safety or effectiveness
Product Code	FRO	FRO	Similar
Regulation Number	Unclassified	Unclassified	Similar
Regulation Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Similar
Intended Use/ Indications for Use	New Day Skin Spray is a skin emulsion indicated for the management of dryness of skin, and atopic dermatitis. New Day Skin Spray maintains a moist skin and wound environment beneficial to the healing process.	EPICERAM is a skin barrier emulsion to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatoses, including atopic dermatitis, irritant contact dermatitis, radiation dermatitis. EPICERAM® helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	Similar
Mechanism of Action	Skin barriers emollient and moisturizer. Skin protector.	Skin barriers emollient and moisturizer	Similar
Delivery System	Emulsion Spray	Emulsion	Provide a physical barrier to protect affected skin areas
Composition	Xanthan Gum and Silk fibroin (Proteoglycan) Water Caprylic/Capric Triglyceride (MCT Oil) Glycerin Sodium Benzoate Citric Acid This product does not contain corticosteroids	Xanthan Gum Petrolatum Dimethicone PEG-100 Stearate Water Capric acid Glycerin Glyceryl Stearate Conjugated Linoleic Acid Palmitic Acid Squalane Hydroxypropyl Bismaleimide MEA (Ceramide) Cholesterol Sorbic Acid Phenoxyethanol Citric Acid Potassium Hydroxide Disodium EDTA	
Sterility	Non-sterile	Non-sterile	Similar
Single Use	Yes	Yes	Similar

7. Performance Summary

Testing was conducted to demonstrate safety and effectiveness of New Day Skin Spray, as well as to establish substantial equivalence to the predicate devices referenced in this pre-market notification. A series of testing was identified and conducted on the subject device, following established protocols to verify that the subject device meets all design requirements. These include biocompatibility, design specifications, preservative effectiveness, microbial tests and evaluation of human repeated insult patch testing and skin prick testing.

The results of testing show that the subject device, New Day Skin Spray, met all performance testing and performed as intended, and did not raise new safety or performance questions.

A. Product Characterization

Device characterization testing was conducted using 3 lots of New Day Skin Spray. Test samples were prepared and tested according to established protocols. Table 2 below summarize the evaluation criteria and results for each device characteristic across the three (3) lots. The results indicated that the device met the acceptance criteria.

The results are shown in Table 2 below.

TABLE 2: DEVICE CHARACTERIZATION

Characteristic	Specification	Pass/Fail
Color	White	Pass
Appearance	Liquid	Pass
pH (USP <791>)	5.0 – 6.0	Pass
Viscosity (Spindle #3, 30rpm)	200 – 2,100 cP	Pass
Microbial Enumeration USP <61>	≤ 200 CFU/g Total Aerobic Microbial Microorganisms	Pass
	≤ 20 CFU/g Total Combined Yeast/Mold count	Pass
USP <62>	Absence in 1 g or 1 ml	Pass

B. Preservative Efficacy Test

The New Day Skin Spray met the USP<51> acceptance criteria for preservative efficacy.

C. Biocompatibility

New Day Skin Spray is a non-sterile, non-steroidal topical device intended for prolonged contact with breached or compromised surfaces. Following the FDA guidance document titled *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, the following tests were conducted and summarized in Table 4.

TABLE 4: SUMMARY OF BIOCOMPATIBILITY TEST

Biocompatibility Tests
ISO 10993-5: Cytotoxicity
ISO 10933-10: Guinea Pig Maximization Sensitization
ISO 10993-23: Skin Irritation
ISO 10993-6: Tests for local effects after implantation
ISO 10993-11: Subacute systemic toxicity
FHSA dermal toxicity study in lieu of ISO 10993-11: Acute Systemic Toxicity
USP<151> Material-Mediated Pyrogenicity

8. Conclusion

The data provided in the 510(k) premarket notification demonstrate that the performance of the subject device, New Day Skin Spray, is substantially equivalent to the legally marketed predicate device, EpiCeram Skin Barrier Emulsion, and does not raise new questions of safety or effectiveness.