September 20, 2024

Raya Pharmaceuticals LLC
Parikh Ankur
Chief Executive Officer
115 Kings Bay Rd
Suite C
Kingsland, Georgia 31548

Re: K240722
Trade/Device Name: Derma-R Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 22, 2024
Received: August 22, 2024

Dear Parikh Ankur:

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.

510(k) Number *(if known)*
K240722

Device Name
Derma-R Cream

Indications for Use *(Describe)*
It is intended for management of pruritus and Dryness of skin in Atopic dermatitis and Allergic contact dermatitis. Not to be used on Breached or Compromised skin or open sores.

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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510K Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92a), the following summary is provided.

Submitter Information:

- 510(k) Submitter: Raya Pharmaceuticals LLC
- Address: 115 Kings Bay Rd, Suite C, Kingsland, Ga, 31548
- Company Contact Person: Ankur Parikh, CEO
  - Phone: (904) 386-6785
  - Fax: 1-877-735-9071
  - Email: office@rayapharmaceuticals.com
- Establishment Registration: 3019944216
- Device Common Name: Dressing, Wound, Drug
- Device trade or proprietary name: Derma-R Cream
- Device Classification: Unclassified
- Device Panel: General & Plastic Surgery
- Device Product Code: FRO
- Primary Predicate Device
  510(k) Number: K090585
  Device Name: Neosalus cream.
  Manufacturer: QUINNOVA PHARMACEUTICALS

Date of Summary Preparation: September 9th, 2024

Device Description

Derma-R Cream is a non-sterile formulation intended for topical application. It is intended for management of pruritus and Dryness of skin in Atopic dermatitis and Allergic contact dermatitis. Not to be used on Breached or Compromised skin or open sores.

Indications for Use

It is intended for management of pruritus and Dryness of skin in Atopic dermatitis and Allergic contact dermatitis. Not to be used on Breached or Compromised skin or open sores.

Comparison of Derma-R Cream and Predicate Device Composition

Derma-R used Component with Similar Chemical Characteristics as the predicate Device. Nonclinical tests showed Derma-R was equivalent to the predicate and a non-irritant, non-sensitizer, and non-Cytotoxic.

Comparison of Derma-R Cream and Predicate Device in terms of Technological Characteristics

Technological Characteristics	**Derma-R**	**Neosalus (K090585)**
Topical Dressing	Same as predicate	Same
Dosage form	Cream	Cream
Emulsifier	Same as predicate	Same
PH Balancer	Same as predicate	Same

Comparison of Derma-R Cream and Predicate Device in terms of Indication for Use

	Derma-R	**Neosalus (K090585)**
Intended Use and Indication for Use	management of pruritus and Dryness of skin in Atopic dermatitis and Allergic contact dermatitis.	Management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.
Rx Only	✓	✓

The Following Biocompatibility tests were conducted:

1- Cytotoxicity testing, per ISO 10993-5:2009 (In Vitro)

2- Skin Sensitization testing, per ISO 10993-23:2021

3- Skin irritation testing, per ISO 10993-10:2021

Other Tests:

Microbiology test

A- USP<61> to Microbial Examination of Non-sterile products: Microbial Enumeration Tests

B- USP<62> Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms

C- In Use Stability Study of Derma - R Cream, to establish a period of time during which product can be used whilst retaining quality within an accepted specification once the container is opened.

D- The Preservative effectiveness test, Per USP <51>.

E- Shelf Life and Stability Tesings.

Clinical Performance Testing
No clinical performance testing was provided to demonstrate device safety and effectiveness.

Conclusion
Based on its formulation, indication for use, as well as the non-clinical and clinical testing results showing a similar profile, we conclude that Derma-R Cream is substantially equivalent to its predicate device Neosalus cream.