October 16, 2017

Founders Science Group, LLC
Ronald Gurge, Ph.D.
Chief Science Officer
30 Robert W. Boyden Road
Suite A1000
Taunton, Massachusetts 02780

Re: K171879
Trade/Device Name: HylaGuard Moisturizing Cream
Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 2, 2017
Received: October 4, 2017

Dear Dr. Gurge:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171879

Device Name
HylaGuard Moisturizing Cream

Indications for Use *(Describe)*
HylaGuard Moisturizing Cream is intended for the dressing and management of minor skin irritations and minor burns, including sunburn.

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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510(k) Summary

I. Submitter

Founders Science Group/Puddingstone Pharma
Regulatory Affairs
30 Robert W. Boyden Road Suite A1000
Taunton, MA 02780
Contact Person: Ronald M. Gurge
Email: rgurge@founderssg.com
Date Prepared: October 11, 2017

II. Device Name

Name of Device:	HylaGuard Moisturizing Cream
Common or Usual Name:	Dressing, Wound, Drug
Panel:	General & Plastic Surgery
CFR Number:	Unclassified
Product code:	FRO

III. Predicate Device

MimyX Cream cleared under 510(k) K041342, from Stiefel Laboratories, Inc.

IV. Device Description

HylaGuard Moisturizing Cream is a non-sterile, off-white, low odor, fragrance free, topical device product. HylaGuard Moisturizing Cream forms a semi-permeable, physical barrier that moisturizes and protects skin. HylaGuard Moisturizing Cream is an over-the-counter (OTC) device. The same device has been cleared for prescription use in K150914 under the name of Dash-Topic Plus Cream.

V. Indications for Use

HylaGuard Moisturizing Cream is intended for the dressing and management of minor skin irritations and minor burns, including sunburn.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed and predicate devices are both semi-viscous oil-in-water emulsions containing humectant and emollient components. These components donate moisture to the skin and form a semi-permeable protective barrier. Both the proposed and predicate device products are non-sterile creams which contain preservatives, and are used topically for management of minor skin irritation or minor burns, including sunburns.

VII. Substantial Equivalence

HylaGuard Moisturizing Cream is similar in function and intended use when compared to MimyX Cream manufactured by Stiefel Laboratories, Inc. HylaGuard Moisturizing Cream has similar OTC indications for use and similar operating principles as the predicate device, MimyX Cream.

VIII. Performance Data

Non-clinical testing was conducted to confirm the safe and effective performance of HylaGuard Moisturizing Cream. Agar Diffusion Cytotoxicity (ISO 10993-5: 2009), Direct Primary Skin Irritation (ISO 10993-10:2010) and Kligman Maximization Sensitization (ISO 10993-10:2010) Tests were performed on the proposed device. The results of the biocompatibility tests demonstrate that HylaGuard Moisturizing cream is non-cytotoxic, a negligible irritant and non-sensitizing. For release and shelf life stability studies, the device had undergone bench performance testing, the following parameters were monitored: Appearance, pH, preservative content, viscosity and package integrity. The device had undergone bench performance testing as per USP<51> (Antimicrobial Effectiveness Testing) and USP<61><62> (Microbial Enumeration Tests and Tests for Specified Microorganisms). In-use stability testing was conducted to determine the use-life of the opened 450g container, the following parameters were monitored during the study: Appearance, pH, preservative content, viscosity, package integrity, USP<51> and USP<61><62>.

IX. Conclusion

The non-clinical performance data confirms the physical characteristics, stability and shelf-life of the proposed device. The biocompatibility testing data confirms the safety of the proposed device. HylaGuard Moisturizing Cream has similar OTC indications, operating principles and similar functioning components when compared to the predicate. Therefore, HylaGuard Moisturizing Cream is substantially equivalent to MimyX Cream, cleared under 510(k) K041342.