



Food and Drug Administration
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April 21, 2016

Founders Science Group, LLC
Ronald M Gurge, Ph.D.
Chief Science Officer
400 Highland Corporate Drive
Cumberland, RI 02864

Re: K150914
Trade/Device Name: Dash-Topic Plus Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 18, 2016
Received: March 21, 2016

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 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" (21CFR 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 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 yours,

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

Indications for Use

510(k) Number (if known)
K150914

Device Name
Dash-Topic Plus Cream

Indications for Use (Describe)

Under the supervision of a healthcare professional, Dash-Topic Plus Cream is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Dash-Topic Plus Cream also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is 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.

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510(k) Summary

I. Submitter

Puddingstone Pharma
Regulatory Affairs
400 Highland Corporate Drive
Cumberland, RI 02864
Contact Person: Robert Munroe
Email: puddingstone@founderssg.com
Date Prepared: March 31, 2015

II. Device Name

Name of Device:	Dash-Topic Plus Cream
Common or Usual Name:	Dressing, Wound, Drug
Classification Name:	Dressing, Wound, Drug
Panel:	General & Plastic Surgery
CFR Number:	Unclassified
Product code:	FRO

III. Predicate Device

HylatopicPlus Cream cleared under 510(k) K110727, from PreCision Dermatology Inc.

IV. Device Description

Dash-Topic Plus Cream is a non-sterile, off-white, low odor, fragrance free, topical product. Dash-Topic Plus Cream forms a physical barrier that helps to maintain a moist wound and skin environment. Dash-Topic Plus Cream is a prescription device.

V. Indications for Use

Under the supervision of a healthcare professional, Dash-Topic Plus Cream is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Dash-Topic Plus Cream also helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

VI. Comparison of Technological Characteristics with the Predicate Device

Both the proposed and predicate device are oil-in-water emulsions containing humectant and emollient components which donate moisture to the skin, and form a semi-permeable protective barrier. Both products are non-sterile creams containing similar preservative systems, and are used topically to relieve symptoms of various dermatoses.

VII. Substantial Equivalence

Dash-Topic Plus Cream is similar in function and intended use to HylatopicPlus Cream manufactured by PreCision Dermatology Inc., and includes identical components, indicated uses and operating principles.

VIII. Performance Data

Non-clinical testing was conducted to confirm the safe and effective performance of Dash-Topic Plus 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 Dash-Topic Plus Cream is non-cytotoxic, a negligible irritant and non-sensitizing. For release and shelf life stability studies, the device product had undergone bench performance testing, the following parameters were monitored: Appearance, pH, preservative content, viscosity and package integrity. The device product had undergone Preservative Effectiveness 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 shelf-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 bench performance data confirms the physical characteristics, stability and shelf-life of the proposed device product. The biocompatibility testing data confirms the safety of the proposed device product. Dash-Topic Plus Cream has identical indicated uses, operating principles and component composition when compared to the predicate. Therefore, Dash-Topic Plus Cream is substantially equivalent to HylatopicPlus Cream, cleared under 510(k) K110727.