DEC 16 2013

510(k) Summary

Submitter	IGI Laboratories, Inc. 105 Lincoln Ave P.O. Box 687 Buena, NJ 08310
Contact Person	Frederick Weiss Vice President, Quality Tel: (856) 697-1441, ext 360 Fax: (856) 697-2259
Date Prepared	November 7, 2013
Trade Name	Hylamix Cream
Common Name	Dressing, Wound, Drug
Classification Name	Dressing, Wound, Drug
Classification Code	FRO
Panel	General & Plastic Surgery
Device Class	Unclassified
Predicate Device	Hylatopic Plus™ Cream; PreCision Dermatology, Inc. 510(k) K110727
Description	Non-sterile, white, fragrance free, topical cream. Hylamix forms a physical barrier which maintains a moist wound and skin environment, and will be marketed in a 100 g tube, and 450 g jar as a prescription device.
Indications for Use	Under the supervision of a healthcare professional, Hylamix 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. Hylamix Cream also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process. Hylamix Cream is indicated for use in: • Atopic Dermatitis • Allergic Contact Dermatitis • Radiation Dermatitis
Device Description and Comparison	A detailed description of the proposed device and its comparison to the predicate device can be found in Sections 11 and 12 of this submission. Both the proposed and referenced predicate device are oil-in-water emulsions, containing humectant and emollient components, which add moisture to the skin, and form a semi-permeable physical barrier which protects the skin from external irritants. Both products are non-sterile creams, and are used topically to relieve symptoms of various dermatoses. A comparison of the intended use and labeling of the proposed and predicate device can be found in Section13.
Substantial Equivalence	The product is similar in function and intended use to Hylatopic Plus™ Cream manufactured by PreCision Dermatology Inc., and includes identical ingredients, indicated uses, and operating principles.
Non-clinical Performance	Non-clinical testing was conducted to confirm the safe and effective performance of Hylamix Cream. Cytotoxicity – Agar Diffusion (ISO 109935:2009), Guinea Pig Sensitization, and Primary Dermal Irritation Tests

	(ISO 10993-10:2010) were performed on the proposed device. Hylamix Cream has been proven to be: Non-Cytotoxic based on Agar Diffusion Test (ISO 10993-5). The subject device elicited a sensitization reaction in guinea pigs and a slight dermal irritation response in rabbits. For the stability studies, the product has undergone chemical and microbiological testing as per USP<51> and USP<61>. The results indicate that in the closed container the product has a 12 month expiration date. Once the tube has been opened the duration of use (expiration date) is 9 months.
Clinical Performance	Several clinical tests were conducted to confirm the safety of Hylamix Cream. Hylamix Cream has been proven to be: Non-indicative to have a potential for dermal irritation based on 48 hours Patch Test on humans, and non-indicative to have a potential for dermal irritation or allergic contact sensitization based on Repeated Insult Patch Test (RIPT) on humans. (Declaration of Helsinki, 21 CFR parts 50 & 56, ICH guideline E6).
Conclusion	Sections 11and 12 describe the substantial equivalence of the proposed device and the predicate device. The non-clinical and clinical data found in sections 5, 6, 7 confirm the safety of the proposed product. Although slight reactions were noted in the animal studies, no negative reactions occurred in the human tests. The identical indicated uses, operating principles and compositions indicate that Hylamix Cream is substantially equivalent to the currently cleared and marketed Hylatopic Plus™Cream.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IGI Laboratories, Incorporated
Mr. Frederick Weiss
Vice President, Quality
105 Lincoln Avenue
P.O. Box 687
Buena, New Jersey 08310

December 16, 2013

Re: K123678
Trade/Device Name: Hylamix Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Weiss:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K123678

Device Name: Hylamix Cream

Indications for Use:

Under the supervision of a healthcare professional, Hylamix 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. Hylamix Cream also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Hylamix Cream in indicated for use in:

- Atopic Dermatitis
- Allergic Contact Dermatitis
- Radiation Dermatitis

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S