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

August 25, 2017

Global Health Solutions, LLC
Bradley Burnam
Founder
1360 Redmond Circle
Rome, Georgia 30165

Re: K171191
Trade/Device Name: Hexagen Derm
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 28, 2017
Received: July 28, 2017

Dear Bradley Burnam:

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)*
K171191

Device Name
Hexagen Derm

Indications for Use *(Describe)*
Hexagen Derm is a topical 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, and radiation dermatitis. Hexagen Derm helps to relieve dry, waxy skin by maintaining a moist wound and 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.

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 for Hexagen Derm

1. Submission Sponsor:
Global Health Solutions, LLC (Owner/Operator: 10050298) 1360 Redmond Circle NW, Rome GA, 30165

2. Submission Contact:
Bradley Burnam, Founder/ CEO
Phone: 818-312-6621 Email: brad@globalhealthrx.com eFax: 818-302-2424

3. Date Prepared: April 23, 2017

4. Device Identification:
Trade Name: Hexagen Derm
Common Name: Topical Emulsion
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Device Class: Unclassified

5. Predicate Device:

PolyPlex Wound Dressing (K160872)
Epiceram Skin Barrier Emulsion (K052643)

6. Description of Proposed Device:
Hexagen Derm is an amorphous, odorless, petrolatum-based emollient consisting of petrolatum (95%), water, and the antimicrobial preservatives Polyhexamethylene Biguanide (PHMB) and Benzalkonium Chloride (BZK). Hexagen Derm's petrolatum base locks in moisture at the skin surface to keep wounded skin moist. Hexagen Derm is non-sterile, RX only, and available in 30 and 90 gram low density polyethylene tubes.

7. Indications for Use Statement:
Hexagen Derm is a topical 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, and radiation dermatitis. Hexagen Derm helps to relieve dry, waxy, skin by maintaining a moist wound and skin environment, which is beneficial to the healing process

8. Performance Testing:
The product is non-cytotoxic, non-sensitizing, and non-irritating per ISO 10993 biocompatibility trials. USP 51 trials confirm that the preservatives are effective.

9. Substantial Equivalence Discussion:

Hexagen Derm is identical in formulation to the predicate product, PolyPlex Wound Dressing (K160872). Hexagen Derm keeps wounded skin moist in an equivalent manner to the predicate product, Epiceram (K052643), which is beneficial to the healing process. Hexagen Derm also incorporates equivalent indications to Epiceram. The product is determined to be substantially equivalent to the predicate devices.