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

November 23, 2015

Oculus Innovative Sciences, Inc.
Mr. Brian W. Martin
Director of Regulatory Affairs and Quality Control
1129 North McDowell Boulevard
Petaluma, California 94954

Re: K152055
Trade/Device Name: Ceramax Skin Barrier Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 2, 2015
Received: November 3, 2015

Dear Mr. Martin:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152055

Device Name
Cermax Skin Barrier Cream

Indications for Use *(Describe)*
INDICATION FOR USE
Under the supervision of a health care professional, Ceramax is intended to be used as a topical skin care preparation to relieve and to manage the burning, and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment.
Ceramax may be used 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.

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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OCULUS
Innovative Sciences

1 510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

510(k) Owner
Oculus Innovative Sciences, Inc.
1129 North McDowell Blvd.
Petaluma, CA 94954
Phone: (707) 283-0550
Fax: (707) 283-0551

Official Contact
Brian W. Martin
Director of Regulatory Affairs and Quality Control

Device Information

Trade or Proprietary Name:	Ceramax Skin Barrier Cream
Common Name:	Wound Dressing
Classification Name:	
Regulation:	21 CFR Unclassified, Pre-amendment status
Product Code(s)	FRO
Device Panel	TBD
Legally marketed device(s) to which equivalence is claimed:	Epiceram K052643, and TL-Cermide K110757
Reason for 510(k) submission	New Device
Device Description	Ceramax emollient formulation is a non-steroidal, non-sterile, off-white, low odor, fragrance free, topical formulation delivers as a cream or a foam. The cream is dispensed via a tube and rubbed into the skin. When the Ceramax formulation is applied to diseased skin protective barrier that helps to maintain a moist wound and skin environment is formed. This device is presented as a prescription product that requires the physician to diagnosis of the disease state and prescribes the product.
Intended Use	Ceramax is intended to be used as a topical skin care preparation to relieve and to manage the burning, and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment. Ceramax may be used to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.
Performance Testing	The following tests were reviewed to support the performance of Ceramax: visual inspection, pH, Viscosity, Bioburden, and Preservative Effectiveness. The Ceramax cream meets specification and performance characteristics and is

substantially equivalent to the predicate devices.

Biocompatibility Testing — Biocompatibility Testing related to Ceramax confirmed that the device meets the applicable requirements of the Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of Medical Devices and is biocompatible.

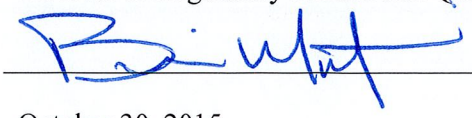
Safety and Effectiveness — Ceramax does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed.

Substantial Equivalence (SE) Rationale

	Ceramax	**Epiceram**	**TL-Cermide**
Regulatory Status	Present application	Predicate	Predicate
510(k) Number	K152055	K052643	K110757
Product Code	FRO	FRO	FRO
Indications for Use	Ceramax is intended to be used as a topical skin care preparation to relieve and to manage the burning, and itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment. Ceramax may be used to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	Epiceram is intended to be used as a topical skin care preparation to relieve and to manage the burning, itching associated with various dermatoses including atopic dermatitis, irritant contact dermatitis, radiation dermatitis and other dry skin conditions, by maintaining a moist wound and skin environment. Epiceram may be used to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.	TL-Cermide Skin Emulsion is to be used to treat dry skin conditions and to manage and relieve the burning and itching associated with various types of dermatitis, including atopic dermatitis, irritant contact dermatitis, and radiation dermatitis. TL-Cermide Skin Emulsion helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.
Sterility	Non-sterile	Non-sterile	Non-sterile
Delivery System	Tube	Tube or Can	Tube

Ceramax is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the Epiceram (K052643) distributed by Puracap Pharmaceuticals. Therefore, the Oculus Ceramax is substantially equivalent to the predicate devices.

Submitted by: Brian W. Martin
Director of Regulatory Affairs and Quality Control



Date Submitted: October 30, 2015