

K052643

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APR 11 2006

510(k) Summary

1. Submission Applicant & Correspondent

Name: Ceragenix Corporation
Address: 1444 Wazee Street
Suite 210
Denver, Colorado 80202

Phone No. (720) 946-6440

Contact Person: Carl Genberg, J.D.

2. Name of Device: EPICERAM® Skin Barrier Emulsion

Trade/Proprietary/Model Name: EPICERAM®

Common or Usual Name: Skin Barrier Emulsion

Classification Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

Devices to Which New Device is Substantially Equivalent:

- Sinclair Wound and Skin Emulsion™ - Sinclair Pharmaceuticals, Ltd (K024367, July 28, 2003);
- Biafene Wound Dressing Emulsion (Radiodermatitis Emulsion) - Medix Pharmaceuticals Americas, Inc. (K964240, Jan. 22, 1997);
- Carrasyn® Hydrogel Wound Dressing, which is also marketed under the name RadiaCare Gel Hydrogel Wound Dressing – Carrington Laboratories, Inc. (K961758, July 11, 1996); and
- Mimyx™ Cream – Steifel Laboratories, Inc. (K041342, July 19, 2005)

3. Device Description:

EPICERAM™ is a non-sterile, viscous, lipid-rich emulsion presented for prescription use.

4. Intended Use of the Device:

The device is intended to be used as a topical skin care preparation applied at least twice daily to affected areas of the skin to improve dry skin conditions and 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.

5. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

All products referenced are non sterile emulsion/gel types that are applied topically to relieve the symptoms of various dermatoses, including, but not limited to atopic dermatitis, irritant contact dermatitis and radiation dermatitis.

6. Tests and Conclusions:

Functional and performance testing has been conducted to assess the safety and effectiveness of EPICERAM™ Skin Barrier Emulsion and the results are satisfactory.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ceragenix Corporation
c/o Mr. Carl Genberg
Senior Vice President, R&D
1444 Wazee Street
Denver, Colorado 80202

Re: K052643
Trade/Device Name: EPICERAM™ Skin Barrier Emulsion
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 17, 2006
Received: January 17, 2006

Dear Mr. Genberg:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K052643

Device Name: EPICERAM™ Skin Barrier Emulsion

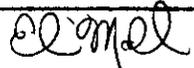
Indications for Use:

FOR TOPICAL DERMATOLOGICAL USE ONLY

EPICERAM® is a skin barrier 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, radiation dermatitis. EPICERAM® helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Apply Epiceram® in a thin layer to the affected skin areas 2 times per day (or as needed) and massage gently into the skin. If the skin is broken, cover Epiceram® with a dressing of choice.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 
Division of General, Restorative,
and Neurological Devices

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Prescription Use X

OR

Over-the-Counter Use _____

(Per 21 C.F.R. § 801.109)