DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 22, 2017

EXELTIS USA Dermatology, LLC
Babu Lad
Vice President of Regulatory Affair
180 Park Avenue, Suite 101
Florham Park, New Jersey 07932

Re: K170911
Trade/Device Name: NEOCERA Advanced Barrier Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 23, 2017
Received: July 19, 2017

Dear Babu Lad:

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" (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 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

~~14 July 2017~~

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)*
K170911

Device Name
Neocera Advanced Cream

Indications for Use *(Describe)*
Indicated for the management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis

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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NeoCera Advanced Cream
510(K) K170911

5 510(k) K170911 Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR 807.87(h) and (21 CFR 807.92a), the following summary is provided.

5.1 Submitter Information

Owner's Name: EXELTIS USA Dermatology, LLC
Address: 180 Park Avenue, Suite 101
Florham Park, NJ 07932
Phone: (973) 324-0200
Fax: (973) 324-0795

Contact Person: Babu Lad, Vice President, Regulatory Affairs

Date of Summary Updated: August 22, 2017

5.2 Product Information

Product Trade Name: NEOCERA™ Advanced Cream

Common Name: Wound Dressing

Device Classification: Unclassified

Product Code: FRO

Device Description

NEOCERA Advanced Cream is a fragrance-free, water-soluble dressing formulated for the management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

NEOCERA Cream is intended for topical application. This product is to be sold by prescription only.

Intended Use and Indications for Use

NEOCERA Cream is indicated for management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.

Predicate Device

The chosen predicate device is Neosalus cream (K090585).

	NEOCERA	**Predicate Neosalus**
Intended Use and Indication for Use	Management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.	Management of various types of dermatoses, including atopic dermatitis and allergic contact dermatitis.
Rx Only	Yes	Yes

Technological Characteristics

NEOCERA Cream is a topical dressing. The chosen predicate device is Neosalus cream (K090585). The two product are very similar in terms of formulation and indication for use. Both device are non-sterile formulations intended for topical application and for prescription use only.
The formulation of NEOCERA Cream helps the product form a semi-occlusive dressing to cover the affected area of the body. The only difference in the formulations of the

NEOCERA Cream and the predicate is the use of additional ingredients in the NEOCERA Cream formulation. These ingredients although new in the formulation, have been previously used in various cleared devices in the same category as NEOCERA Cream and the Predicate. The ingredients were added to enhance the ease of application. More information has been provided on the additional ingredients in section 10 of this 510 (k) submission (Executive Summary)

Comparison of technological Characteristics between NEOCERA Cream and the Predicate

Technological Characteristics	**NEOCERA**	**Neosalus**
Topical Dressing	Same	Same
Composition	Similar to predicate	Similar
Skin conditioning agents to enhance appearance of dry skin	Present	None
Film Former	Present*	Present
Preservatives	Present	Present
Emulsifier	Present	Present

***** In higher quantity than in predicate (see Table 10.2, Page 32 of original submission)

Comparison of NEOCERA Cream and Predicate Device Composition

Ingredient	Function	NEOCERA	Neosalus	Medical devices Use
Purified Water	Solvent	QS	QS	Predicate
Carbomer 980	Thickening agent	0.7	0.7	Predicate
Stearic Acid	Emulsifying agent	6.25	6.25	Predicate
Glycerin	Humectant	1.7	1.7	Predicate
Propylene Glycol	Humectant	5.8	5.8	Predicate
Polysorbate 20	Emulsifying agent	1.4	1.4	Predicate
Plasdone	Film former	--	1.9	Predicate
Triethanolamine	Emulsifying agent and pH buffer	1	1.3	Predicate
Phenonip XB	Preservative	0.5	0.5	Predicate
Sodium Hydroxide	pH adjuster	0.008	0.2	Predicate
Dimethicone@	Film former	5	0.95	Predicate
Petrolatum	Film former	5	--	Hylatopic Plus Cream (K110727)
Ceramide PC-104 *	Skin conditioning agent	0.5	--	Hylatopic Plus Cream (K110727)
Palmitamide MEA	Viscosity builder; Skin conditioning agent	0.01	--	Mimyx Cream (K041342)
Glycerrhetinic Acid	Skin conditioning agent	0.4	--	Pruclair Cream (K09156) Promiseb Cream (K050158)
Grape seed extract**	Antioxidant	0.1	--	Pruclair Cream (K09156) Promiseb Cream

@ Dimethicone is accepted for human use in OTC monograph from 1% to 30% [21 CFR 347.10 (g)]
Petroleum and Ceramide

Performance Data

The predicate device is a non-sterile formulation that is applied topically for the management and relief of irritation associated with various types of dermatoses. Non-clinical testing as well as clinical testing were conducted to establish that NEOCERA has a safety and biocompatibility profile similar to the predicate device.

Non-Clinical testing

- Cytotoxicity – Agar Diffusion - Report No. V15-2677 (see section 15. Biocompatibility Page 312)

  Cytotoxicity testing was performed under Good Laboratory Practice (GLP) Standards and per ISO 10993-5, part 5: Test for In Vitro Cytotoxicity. The testing demonstrated that NEOCERA cream meets the requirement of the test per ISO 10993-5, and therefore is not cytotoxic.

- Primary Dermal Irritation in Rabbits – Report No. T15-1205-01 (see section 15. Biocompatibility Page 312)

  Irritation testing was performed under GLP standards and also according to ISO 10993-10, Biological Evaluation of Medical devices- Part 10: Test for Irritation and Sensitization. The test article, NEOCERA Cream Elicited a primary dermal irritation index of 0.67 on a scale of 0-8. A primary dermal irritation index of 0.67 is categorized as being slightly irritant. We would like to point out that slightly irritant category ranges from 0.5-1.9, and clearly the test article NEOCARA Cream is at the lower end of the range.

- Guinea Pig Closed Patch Sensitization Test – Report No. T15-1205-2 (see section 15. Biocompatibility Page 313)

  Sensitization testing was also performed under GLP standards and per ISO 10993-10, Biological Evaluation of Medical devices- Part 10: Test for Irritation and Sensitization. Under the conditions of the testing, the test article did not elicit a sensitization reactions in the guinea pigs.

Clinical testing

- Repeated Insult Patch Test in Humans – Report No. C15-1204.01 (see section 15. Biocompatibility Page 313)

  This test was perform in accordance with the Declaration of Helsinki, ICH E6, and 21 CFR Parts 50 and 56. The test article NEOCERA Cream did not demonstrate any potential for dermal irritation or allergic contact sensitization in humans.

Biocompatibility Sterilization and Shelf Life

	NEOCERA	Neosalus
Biocompatibility (Non – clinical and Clinical testing)	Similar	Similar
Sterilization	Non- Sterile	Non-Sterile
Antimicrobial Efficacy Testing	Meet requirement	Meet requirement
Shelf Life	24 months (on going Stability)	36 months

Conclusion

Based on its formulation, indication for use, as well as the non-clinical and clinical testing results showing a similar safety profile, we conclude that NEOCERA Cream is substantially equivalent to its predicate device Neosalus cream.