August 13, 2018

Valeant Pharmaceuticals
Esha Desai
Senior Manager Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Re: K173549
Trade/Device Name: Biafine
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 9, 2018
Received: July 11, 2018

Dear Esha Desai:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

510(k) Number *(if known)*

K173549

Device Name
BIAFINE

Indications for Use *(Describe)*

OTC Indications and Usage:
BIAFINE is indicated for management of superficial wounds such as minor cuts, minor scrapes, minor irritations, minor abrasions, minor blisters, 1st degree burns including sunburns, minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels.
BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.

RX Indications and Usage:
BIAFINE is indicated for management of full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers, radiation dermatitis, donor sites and 2nd degree burns.
BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.

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.

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1 510(k) SUMMARY

1. General Information

Submitter: Valeant Pharmaceuticals 1400 North Goodman Street Rochester, NY 14609 General Telephone: 585-338-5800	Contact Person: Esha Desai 400 Somerset Corporate Blvd. Bridgewater, NJ 08807 908-541-3273 Esha.Desai@valeant.com

Preparation Date: August 13, 2018

2. Names

Device Name: BIAFINE Topical Cream
Classification Name: Dressing, Wound and Burn, Hydrogel W/Drug And/Or Biologic
Common Name: Wound Dressing
Product Codes: FRO
Performance Standards: No performance standards for this device have been promulgated under Section 514, Federal Food, Drug and Cosmetics Act.

3. Predicate Devices

BIAFINE cleared under K964240 on January 22, 1997
Microcyn Plus Skin and Wound Hydrogel cleared under K153648 on April 19, 2016.
Sockit Dermal Gel cleared under K090092 on May 11, 2009

Reference Device
OxyBand cleared under K043063 on March 24, 2005

4. Product Description

The subject of this 510(k) submission is for the BIAFINE Topical Cream which is substantially equivalent to the predicate. BIAFINE Topical Cream is identical to the formulation, intended use, technology and the performance of the existing product currently commercialized.

Ingredients: Purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (as potassium salt), propyl paraben (sodium salt), and fragrance.

BIAFINE is a white oil-in-water cream and is supplied in lined aluminum tubes with a screw-top closure.

5. Indications for Use

R_X Indications and Usage:

BIAFINE is indicated for management of full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers, radiation dermatitis, donor sites and 2nd degree burns.

BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.

OTC Indications:

BIAFINE is indicated for management of superficial wounds such as minor cuts, minor scrapes, minor irritations, minor abrasions, minor blisters, 1st degree burns including sunburns, minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.

6. Summary of Technological Characteristics

The technological characteristics of the BIAFINE Topical Cream are substantially equivalent to those of the predicate devices. All three products are non-sterile water based, preserved, semi-viscous formulations which have similar indications for use and storage. BIAFINE and Microcyn retain a neutral pH, and are used topically in addition both contain humectant and emollient components which donate moisture to the skin.

	Subject Device	Predicate Device	Predicate Device	Predicate Device	**Reference Device**
Characteristic	Subject Device BIAFINE Topical Cream	K964240 BIAFINE Topical Cream	K153648 Microcyn Skin & Wound Hydrogel	K090092 Sockit Dermal Gel	**Reference Device OxyBand (K043063)**
Intended Use	A wound dressing which creates a moist wound environment necessary to the healing process.	Identical as subject device	Identical as subject device	Identical as subject device	Identical as subject device
R_X Indications for Use	BIAFINE is indicated for the management of:	BAIFINE is intended to be used as a wound dressing for the following	Under the supervision of a health care professional Microcyn Plus Wound Gel is	This product provides for the management of and relieves the pain associated with all types of	The Prescription OxyBand ™ Wound Dressings are intended to

	• Full Thickness Wounds • Pressure Sores • Dermal Ulcers including lower leg ulcers • Radiation Dermatitis • Donor Sites 2nd Degree burns BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.	indications: Superficial wounds Minor Abrasions Leg Ulcers Donor Sites 1st and 2nd degree burns, including sunburn Radiation Dermatitis Dermal ulcers Full Thickness Wounds Pressure Sores	intended for the management of post non ablative laser therapy procedures, post microdermabrasion therapy and following superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns.	dermal wounds, skin sores, injuries and ulcers of the skin. Examples include: • All types of dermal wounds, skin sores, injuries and ulcers of the skin • First & Second degree burns • Pressure ulcers, stages I - IV • Stasis ulcers • Diabetic ulcers • Radiation dermatitis • Post-surgical incision • Surgical sites, including soft tissue graft sites • Foot ulcers • Venous stasis ulcers • Cuts & Abrasions • Partial thickness wounds • Irritation of the skin • Itching • Sunburn • Skin condition associated periostomy care • Chemical peel • Tattooing procedures • Irritation and pain following skin Laser resurfacing treatment • Irritation and	provide a moist environment to facilitate the normal wound healing process. OxyBand ™ Wound Dressings can be used to cover and protect wounds and catheter sites or used as a secondary dressing for other wound products such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at risk skin. The OxyBand ™ Wound Dressings are indicated for: • Clean closed surgical incisions • Skin graft donor sites • Stage I or II pressure ulcers, pressure sores, • Superficial wounds such as abrasions, skin tears, and blisters, lacerations • First and second

				pain following dermabrasion therapy	degree burns • Chafed skin, skin continuously exposed to moisture • Secondary dressing over gauze, alginates or hydrogels
OTC Indications for Use	BIAFINE is indicated for management of • Superficial Wounds such as minor cuts, minor scrapes, minor irritations, minor abrasions and minor blisters • 1st Degree burns, including sunburns • Minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.	Same as R_X indications in clearance letter.	Microcyn Plus Wound Gel is intended for the management of minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels. Microcyn Plus Wound Gel may also be used to relieve itch and pain from minor skin irritations, lacerations, abrasions and minor burns	This product provides for the management of and relieves the pain associated with all minor dermal wounds, minor skin sores, minor injuries and minor irritations of the skin. Examples include: • Minor burns • Minor Cuts & Abrasions • Superficial itching • Sunburn • Minor burns from a chemical peel treatment • Minor irritation and pain following tattooing procedures • Minor irritation and pain following skin laser resurfacing treatment • Minor irritation and pain following dermabrasion therapy	The Over-The-Counter OxyBand™ Wound Dressings are intended to protect light to moderate wounds, including skin tears, scrapes, minor pressure sores, abrasions, blisters, lacerations, minor bums, to protect chafed or irritated skin or skin continuously exposed to moisture, and to create a moist environment for wound healing

Sterility Claim	Non-sterile	Identical as subject device	Identical as subject device	Non-sterile Natural Preservative Gel from food grade components	Identical as subject device
Mechanism of Action	Maintains a moist wound environment'	Identical as subject device	Identical as subject device	Identical as subject device	Supplies oxygen to the wound
Delivery System	Topical Cream	Identical as subject device	Topical Hydrogel	Topical Hydrogel	permeable gas emitting reservoir

7. Safety and Effectiveness Information

   The review of the indications for use and technical characteristics provided demonstrates that BIAFINE Topical Cream is substantially equivalent to the predicate devices.

8. Performance Data

   Non-Clinical Performance Data:

   Non-clinical testing was conducted to support the safety and effectiveness of BIAFINE Topical Cream. An in-use study was performed to support the shelf-life of opened product. Preservative effectiveness testing of BIAFINE Topical cream conducted as per USP <51>. The preservative effectiveness of BIAFINE Topical Cream meet USP <51> criteria. pH, Residual testing, Sulfated Ash, Viscosity and Water Content limit testing were conducted to support the In-Use study data and preservative efficacy as per USP <51> and the results meet the criteria as per USP <51>.

   Clinical Performance Data:

   Clinically, the expanded use of BIAFINE OTC for cosmetic procedures and blister indications and the current general use of the marketed BIAFINE is the same: to aid the natural wound healing process by providing an optimum moist environment. Cosmetic procedures such as post-laser therapy, chemical peeling and dermabrasion treatment stimulate like wound healing processes as each of these procedures enhance skin rejuvenation to fight signs of skin aging as well as treat various dermatologic pathologies, such as acne, melasma, and photodamage.[1,2] Whether a wound is acute or chronic, caused by pressure or burns, scientists and medical professionals recognize that a moist environment can support the natural process of wound healing in all types of wounds.[3,4] Therefore, the same data and results from BIAFINE prescription (Rx) product on wound healing as well as published literature on the benefits of BIAFINE in various wound types including minor blisters and minor skin irritations following post non-ablative laser therapy procedures, are considered applicable for support of expanded indications of BIAFINE for OTC (over the counter) use .
   Multiple independent clinical studies have been reported in the scientific literature on BIAFINE. BIAFINE has been shown effective in wound management of post non-ablative laser procedures,[2,5,6,7,8,9,10] chemical peeling[1] and minor wounds, skin irritation, [1,7,10,11,12,13,14,] and blisters,[11,12,14,15] as well as relief of wound symptoms, such as burning, pain and itch.[7,11,12,13,14,15]

   The results of the published studies on post laser treatment with BIAFINE showed successful management of the side effects (both signs and symptoms) from phototherapy, including crusting, redness, and temporary discomfort.[7] A blinded pilot study evaluated erythema, edema and scarring with BIAFINE use post-laser treatment.[8] In another study, BIAFINE was used post 3DEEP non-ablative skin tightening treatment followed by a Fractional skin

resurfacing treatment. There were no incidences of infections, scarring, hyper/ hypopigmentation, or any other serious complications or any unexpected adverse effects were detected or reported.[9] BIAFINE was tested in a single-center, split-face, double-blind, randomized trial comparing reduction of post treatment redness and peeling versus petrolatum ointment (PBO) after the Microlaser Peel procedure and a treatment with a 2940-nm Er:YAG laser. In this study, BIAFINE achieved a reduction in redness and peeling and appears to be equivalent to PBO in resolving redness and peeling produced by MicroLaserPeel procedures.[10]

Published results from a randomized, single-center, double-blind, split-face clinical study evaluated BIAFINE compared to a placebo cream in 20 volunteers after 5-ALA (aminolevulinic acid) and PDT (photodynamic therapy) treatment. This study also evaluated subjective assessments for itching and tenderness. The assessments showed that BIAFINE topical emulsion appeared to be equivalent on itching, tenderness and peeling at Week 1.[13] Relief of pain and itch from BIAFINE was also shown in several radiation dermatitis studies. One study compared BIAFINE versus petrolatum as supportive care for patients with head and neck cancer (HNSCC) undergoing radiation therapy with concurrent chemotherapy. The study was conducted to assess the anticipated skin reactions and subjective symptoms that regularly involve pain and itch (the same symptoms of pain, itch and burn that are associated with superficial wounds, minor abrasions, 1st degree burns, including sunburns) and blisters, one of the signs of radiation dermatitis. The study showed the use of BIAFINE can effectively manage the acute irradiation induced dermal injury and associated symptoms. [14]

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The collective safety data and the in-use clinical testing results found in the literature on blisters, relief of pain, itch, burn, and in non-ablative, chemical peel and dermabrasion procedures, demonstrates that the predicate devices (BIAFINE (510(k) K964240), OxyBand (510(k): K043063), Microcyn Plus Skin and Wound Hydrogel (510(k) K153648) and Sockit Dermal Gel (510(k) K090092) and the subject (BIAFINE OTC) device can be used effectively for the added indications.

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References

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16. Data on file.

9. Conclusion

BIAFINE Topical Cream shares similar indications for use, identical formulation, manufacturing process, design features, and functional features, and thus is substantially equivalent to, the predicate device BIAFINE**.** Additionally, Preservative Efficacy testing and In-Use study has been conducted to ensure the substantial equivalenceof the product. Thus, the proposed new indications and updated labeling does not adversely affect the performance of BIAFINE.

BIAFINE is substantially equivalent in intended use, technological characteristics and safety and efficacy to the Microcyn Plus Hydrogel (K153648) and Sockit Dermal Gel (K090092), and is therefore substantially equivalent.