October 18, 2019

Bausch Health Americas Incorporated
Marci Halevi
Director, Regulatory Affairs, Surgical Equipment and Devices
1400 N. Goodman St. 14609 USA
Rochester, New York 14609

Re: K190342
Trade/Device Name: BIAFINE Topical Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 19, 2019
Received: September 20, 2019

Dear Marci Halevi:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

For Cynthia J. Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K190342

Device Name
BIAFINE Topical Cream

Indications for Use (Describe)
OTC Indications and Usage: BIAFINE Topical Cream 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 Topical Cream 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(K) SUMMARY

General Information

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Contact Person</th>
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<tbody>
<tr>
<td>Bausch Americas, Inc.</td>
<td>Marci Halevi</td>
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<tr>
<td>1400 North Goodman Street</td>
<td>Director, Regulatory Affairs</td>
</tr>
<tr>
<td>Rochester, NY 14609</td>
<td>Surgical Equipment &amp; Devices</td>
</tr>
<tr>
<td>General Telephone: 585-338-5800</td>
<td>400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807</td>
</tr>
</tbody>
</table>

Preparation Date: October 18, 2019

Device Name: BIAFINE Topical Cream

Classification Name: Dressing, Wound, Drug

Classification: Unclassified

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.

Predicate Devices
BIAFINE Topical Cream was cleared under K173549 on August 13, 2018

Product Description
The subject of this submission is the BIAFINE Topical Cream which is substantially equivalent to the predicate. BIAFINE Topical Cream is identical in formulation, intended use, technology and performance of the existing product currently commercialized.

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

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the BIAFINE Topical Cream are substantially equivalent to those of the predicate devices and are summarized in the table below.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate Device (K173549) BIAFINE Topical Cream</th>
<th>Subject Device (K190342) BIAFINE Topical Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use</strong></td>
<td>A wound dressing which creates a moist wound environment necessary to the healing process.</td>
<td>Identical to Predicate Device</td>
</tr>
<tr>
<td><strong>OTC Indications for Use</strong></td>
<td>BIAFINE Topical Cream 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 Topical Cream may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.</td>
<td>Identical to Predicate Device</td>
</tr>
<tr>
<td><strong>Sterility Claim</strong></td>
<td>Non-sterile, conforming to USP &lt;51&gt;</td>
<td>Identical to Predicate Device</td>
</tr>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Maintains a moist wound environment</td>
<td>Identical to Predicate Device</td>
</tr>
<tr>
<td><strong>Delivery System</strong></td>
<td>Topical Cream</td>
<td>Identical to Predicate Device</td>
</tr>
<tr>
<td><strong>Shelf Life &amp; Use Life</strong></td>
<td>12 Month Shelf Life 30 Day Use Life</td>
<td>12 Month Shelf Life 12 Month Use Life</td>
</tr>
</tbody>
</table>
Performance Data
Previously submitted non-clinical testing, including biocompatibility and (closed tube) shelf life data, continue to support BIAFINE Topical Cream. Additional stability testing was conducted to extend the use-life and support multi-use labeling.

Conclusion
BIAFINE Topical Cream shares the same indications for use, identical formulation, identical manufacturing processes, identical mechanism of action and functional features as the predicate BIAFINE Topical Cream and thus is substantially equivalent to the predicate BIAFINE Topical Cream.

BIAFINE Topical Cream is substantially equivalent in intended use, technological characteristics and safety and effectiveness to the BIAFINE Topical Cream (K173549).