

**K190342 BIAFINE Topical Cream**Oct 18, 2019  
246 days to decisionK190342 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190342/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 14, 2019
Decision date	Oct 18, 2019
Days to decision	246 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bausch Health Americas Incorporated</b>
Location	Rochester, NY, US
Contact	Marci Halevi
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k190342/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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