

K173549 BIAFINEAug 13, 2018
270 days to decisionK173549 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 16, 2017
Decision date	Aug 13, 2018
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Valeant Pharmaceuticals
Location	Rodchester, NY, US
Contact	Melissa Thomas
510(k) history	1 submissions · 1 cleared · 2018-2018

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