

K132329 NIVATOPIC PLUSDec 20, 2013
147 days to decisionK132329 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k132329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jul 26, 2013
Decision date	Dec 20, 2013
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nivagen Pharmaceuticals, Inc.
Location	Lake Wiley, SC, US
Contact	LARA NOAH
510(k) history	1 submissions · 1 cleared · 2013-2013

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