

**K093051 HYLATOPIC PLUS EMOLLIENT FOAM**Dec 7, 2009  
68 days to decisionK093051 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k093051/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 30, 2009
Decision date	Dec 7, 2009
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Collegium Pharmaceutical Incorporated</b>
Location	Cumberland, RI, US
Contact	RONALD M GURGE
510(k) history	3 submissions · 3 cleared · 2009-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093051/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 21, 2026