

**K063517 HEALADEX-P**Feb 16, 2007  
87 days to decisionK063517 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k063517/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 21, 2006
Decision date	Feb 16, 2007
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healagenics, Inc.</b>
Location	Woburn, MA, US
Contact	PAUL STRATI
510(k) history	1 submissions · 1 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063517/> 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 28, 2026