

**K133600 COEUR, INC. FRONTLOAD FOR OPTIVANTAGE  
POWER INJECTOR**Apr 30, 2014  
156 days to decisionK133600 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133600/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 25, 2013
Decision date	Apr 30, 2014
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coeur, Inc.</b>
Location	Lebanon, TN, US
Contact	DEBRA F MANNING
510(k) history	14 submissions · 14 cleared · 2005-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133600/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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