

**K161471 MR Syringe Dual Pack for Solaris Injectors**Oct 6, 2016  
132 days to decisionK161471 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161471/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	May 27, 2016
Decision date	Oct 6, 2016
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coeur, Inc.</b>
Location	Lebanon, TN, US
Contact	Priscilla Cliner
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/k161471/> 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 1, 2026