

**K153141 DyeVert Contrast Modulation System**Feb 4, 2016  
97 days to decisionK153141 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153141/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 30, 2015
Decision date	Feb 4, 2016
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osprey Medical, Inc.</b>
Location	Eden Prairie, MN, US
Contact	MELANIE HESS
510(k) history	14 submissions · 14 cleared · 2013-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153141/> 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 29, 2026