

**K190102 DyeVert™ Plus Contrast Reduction System, DyeTect™ Contrast Monitoring System, DyeVert™ Plus EZ Contrast Reduction System**

Oct 17, 2019  
268 days to decision

K190102 · Product code: **DXT** · General Hospital  
Source: <https://www.510kdatabase.net/k190102/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jan 22, 2019
Decision date	Oct 17, 2019
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	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/k190102/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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