

K181936 DyeVert PLUS EZ Contrast Reduction SystemOct 25, 2018
98 days to decisionK181936 · Product code: **DXT** · CardiovascularSource: <https://www.510kdatabase.net/k181936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jul 19, 2018
Decision date	Oct 25, 2018
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osprey Medical, Inc.
Location	Eden Prairie, MN, US
Contact	Vic Fabano
510(k) history	14 submissions · 14 cleared · 2013-2019

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