

K183267 DyeVert™ NG Contrast Reduction System, DyeVert™ PLUS EZ Contrast Reduction System, DyeTect™ Contrast Monitoring Disposable Kit, Smart Syringe, DyeVert™ PLUS EZ Contrast Reduction SystemDec 20, 2018
27 days to decisionK183267 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k183267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 23, 2018
Decision date	Dec 20, 2018
Days to decision	27 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	Melanie Hess
510(k) history	14 submissions · 14 cleared · 2013-2019

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