

K161505 DyeVert NG Contrast Modulation SystemAug 3, 2016
63 days to decisionK161505 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k161505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 1, 2016
Decision date	Aug 3, 2016
Days to decision	63 days
Third-party review	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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