FDA 510(k) Premarket Notification

K171217 DyeVert Plus Contrast Reduction System, DyeVert NG Contrast Reduction System

CLEARED

May 26, 2017
30 days to decision

K171217 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k171217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 26, 2017
Decision date	May 26, 2017
Days to decision	30 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k171217/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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