FDA 510(k) Premarket Notification

K153141 DyeVert Contrast Modulation System

CLEARED

Feb 4, 2016
97 days to decision

K153141 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k153141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 30, 2015
Decision date	Feb 4, 2016
Days to decision	97 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