FDA 510(k) Premarket Notification

CLEARED

K163054 DyeVert Plus Contrast Modulation/Monitoring System, Contrast Monitoring System

Mar 8, 2017
127 days to decision

K163054 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k163054/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 1, 2016
Decision date	Mar 8, 2017
Days to decision	127 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