FDA 510(k) Premarket Notification

CLEARED

K190102 DyeVert™ Plus Contrast Reduction System, DyeTect™ Contrast Monitoring System, DyeVert™ Plus EZ Contrast Reduction System

Oct 17, 2019
268 days to decision

K190102 · Product code: **DXT** · General Hospital
Source: https://www.510kdatabase.net/k190102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jan 22, 2019
Decision date	Oct 17, 2019
Days to decision	268 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