K142081 CONTRAST MONITORING SYSTEM DISPLAY, CONTRAST MONITORING SYSTEM SYRINGES

CLEARED

Dec 12, 2014
134 days to decision

K142081 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k142081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jul 31, 2014
Decision date	Dec 12, 2014
Days to decision	134 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/k142081/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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