FDA 510(k) Premarket Notification

K150902 330psi Extension Y-Line with Dual Check Valve

CLEARED

Oct 22, 2015
202 days to decision

K150902 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k150902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 3, 2015
Decision date	Oct 22, 2015
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coeur, Inc.**
Location	Lebanon, TN, US
Contact	Erin Rheinscheld
510(k) history	14 submissions · 14 cleared · 2005-2017