FDA 510(k) Premarket Notification

K130124 CATALYST II AND III

CLEARED

Mar 14, 2013
56 days to decision

K130124 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k130124/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Jan 17, 2013
Decision date	Mar 14, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiva Medical, Inc.**
Location	Pleasanton, CA, US
Contact	MICHAEL A DANIEL
510(k) history	7 submissions · 7 cleared · 2004-2013