FDA 510(k) Premarket Notification

K123041 VASOSTAT HEMOSTASIS DEVICE

CLEARED

May 29, 2013
243 days to decision

K123041 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k123041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Sep 28, 2012
Decision date	May 29, 2013
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Forge Medical, Inc.**
Location	Wayne, NJ, US
Contact	MASON DIAMOND
510(k) history	2 submissions · 2 cleared · 2013-2016