FDA 510(k) Premarket Notification

K133029 ABDOMINAL AORTIC AND JUNCTIONAL TOURNIQUET (AAJT) DEVICE

CLEARED

Dec 6, 2013
71 days to decision

K133029 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k133029/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Sep 26, 2013
Decision date	Dec 6, 2013
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Compression Works, LLC**
Location	Providence, RI, US
Contact	MICHAEL FORSTADT
510(k) history	2 submissions · 2 cleared · 2011-2013