FDA 510(k) Premarket Notification

K132545 MEDIVALVE ACWIRE

CLEARED

Nov 8, 2013
87 days to decision

K132545 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k132545/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 13, 2013
Decision date	Nov 8, 2013
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medivalve , Ltd.**
Location	Providence, RI, US
Contact	LEO BASTA
510(k) history	1 submissions · 1 cleared · 2013-2013