FDA 510(k) Premarket Notification

K170684 Firebow Wire Torque Assist Device

CLEARED

Jun 29, 2017
114 days to decision

K170684 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k170684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 7, 2017
Decision date	Jun 29, 2017
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vesatek, LLC**
Location	Irvine, CA, US
Contact	David Look
510(k) history	2 submissions · 2 cleared · 2017-2020