FDA 510(k) Premarket Notification

K141218 ZIGIWIRE MODE2 GUIDEWIRE WIRE SYSTEM, ZIGIWIRE MODE3 GUIDEWIRE WIRE SYSTEM

CLEARED

Dec 18, 2014
220 days to decision

K141218 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k141218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 12, 2014
Decision date	Dec 18, 2014
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vadiswire Corporation**
Location	Kirkland, WA, US
Contact	EDWARD (TED) WULFMAN
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141218/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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