

K153397 S-Wire Guidewire SystemAug 18, 2016
268 days to decisionK153397 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k153397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 24, 2015
Decision date	Aug 18, 2016
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Concert Medical, LLC
Location	Ayer, MA, US
Contact	Timothy S. Powers
510(k) history	3 submissions · 3 cleared · 2009-2016

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