FDA 510(k) Premarket Notification

K152991 OptoWire Deux

CLEARED

Feb 11, 2016
121 days to decision

K152991 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k152991/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 13, 2015
Decision date	Feb 11, 2016
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Opsens**
Location	Quebec, CA
Contact	Vanessa Mootoosamy
510(k) history	1 submissions · 1 cleared · 2016-2016