

K153530 Bridge Occlusion BalloonFeb 5, 2016
58 days to decisionK153530 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k153530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 9, 2015
Decision date	Feb 5, 2016
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectranetics, Inc.
Location	Colorado Springs, CO, US
Contact	Christopher McLellan
510(k) history	17 submissions · 16 cleared · 2014-2022

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