

K203540 Bridge Occlusion BalloonDec 23, 2020
20 days to decisionK203540 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k203540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 3, 2020
Decision date	Dec 23, 2020
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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