

K183679 Occlusion Balloon CatheterApr 24, 2019
117 days to decisionK183679 · Product code: **MJN** · CardiovascularSource: <https://www.510kdatabase.net/k183679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 28, 2018
Decision date	Apr 24, 2019
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qxmedical, LLC
Location	St. Paul, MN, US
Contact	Fernando Di Caprio
510(k) history	5 submissions · 5 cleared · 2012-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183679/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026