

K200459 pREBOA-PRO CatheterJun 3, 2020
99 days to decisionK200459 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k200459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Feb 25, 2020
Decision date	Jun 3, 2020
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Prytime Medical Devices, Inc.
Location	Boerne, TX, US
Contact	Brian Young
510(k) history	5 submissions · 5 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200459/> 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 May 26, 2026