

K193440 ER-REBOA PLUS CatheterJan 9, 2020
29 days to decisionK193440 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k193440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 11, 2019
Decision date	Jan 9, 2020
Days to decision	29 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

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