

**K172790 ER-REBOA Catheter**Nov 8, 2017  
54 days to decisionK172790 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172790/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Sep 15, 2017
Decision date	Nov 8, 2017
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172790/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026