

**K160598 REBOA Balloon Catheter**Jun 20, 2016  
110 days to decisionK160598 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160598/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Mar 2, 2016
Decision date	Jun 20, 2016
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NuMED, Inc.</b>
Location	Hopkinton, NY, US
Contact	NICHELLE LAFLESH
510(k) history	49 submissions · 47 cleared · 1985-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160598/> 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 June 2, 2026