

**K183045 Eclipse 2L**Apr 30, 2019  
179 days to decisionK183045 · Product code: **MJN** · Neurology  
Source: <https://www.510kdatabase.net/k183045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Nov 2, 2018
Decision date	Apr 30, 2019
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Balt USA, LLC</b>
Location	Irvine, CA, US
Contact	Nancy Xu
510(k) history	18 submissions · 18 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183045/> 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 24, 2026