

K182337 HYBRID GuidewireOct 4, 2018
37 days to decisionK182337 · Product code: **MOF** · Neurology
Source: <https://www.510kdatabase.net/k182337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Aug 28, 2018
Decision date	Oct 4, 2018
Days to decision	37 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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