

K182918 Ballast 088 Long SheathMar 21, 2019
153 days to decisionK182918 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k182918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 19, 2018
Decision date	Mar 21, 2019
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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