

K182660 GaltTWSMay 30, 2019
247 days to decisionK182660 · Product code: **DRB** · CardiovascularSource: <https://www.510kdatabase.net/k182660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet, Catheter (DRB)
Date received	Sep 25, 2018
Decision date	May 30, 2019
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Galt Medical Corp.
Location	Garland, TX, US
Contact	David Derrick
510(k) history	14 submissions · 12 cleared · 1999-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182660/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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