

**K192422 Steerable Introducer 12F**Oct 4, 2019  
30 days to decisionK192422 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Sep 4, 2019
Decision date	Oct 4, 2019
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Freudenberg Medical, LLC</b>
Location	Jeffersonville, IN, US
Contact	Mary Prunty
510(k) history	3 submissions · 3 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192422/> 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 25, 2026