

**K233708 NaviGo 12F Steerable Intracardiac Catheter Introducer Kit (S12FS-01)**Feb 16, 2024  
88 days to decisionK233708 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k233708/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 20, 2023
Decision date	Feb 16, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synaptic Medical Corporation</b>
Location	Carlsbad, CA, US
Contact	Jake Harandi
510(k) history	4 submissions · 4 cleared · 2022-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233708/> 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 14, 2026