

**K151396 MIVI Mi-AXUS Guide Catheter**Dec 9, 2015  
197 days to decisionK151396 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k151396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 26, 2015
Decision date	Dec 9, 2015
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mivi Neuroscience, Inc.</b>
Location	Eden Prairie, MN, US
Contact	Matthew Ogle
510(k) history	5 submissions · 5 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151396/> 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 26, 2026