

**K152498 SoloPath Re-Collapsible Access System**Jan 5, 2016  
126 days to decisionK152498 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k152498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 1, 2015
Decision date	Jan 5, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Onset Medical Corporation</b>
Location	Mission Viejo, CA, US
Contact	Monika McDole-Russell
510(k) history	8 submissions · 8 cleared · 2005-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152498/> 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 June 3, 2026