

**K180081 RAILWAY Sheathless Access System**Apr 18, 2018  
97 days to decisionK180081 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 11, 2018
Decision date	Apr 18, 2018
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corporation</b>
Location	Warren, NJ, US
Contact	Michelle Ragozzino Rodgers
510(k) history	13 submissions · 12 cleared · 2004-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180081/> 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 27, 2026