

**K202167 Brite Tip Radianz Guiding Sheath**Feb 26, 2021  
207 days to decisionK202167 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k202167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 3, 2020
Decision date	Feb 26, 2021
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corporation</b>
Location	Warren, NJ, US
Contact	Crystal Placona
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/k202167/> 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