

**K203179 Fortress Introducer Sheath System**Nov 20, 2020  
25 days to decisionK203179 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k203179/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Oct 26, 2020
Decision date	Nov 20, 2020
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contract Medical International, GmbH</b>
Location	Dresden, DE
Contact	Marketa Shanelova
510(k) history	7 submissions · 7 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203179/> 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