

**K221914 Catapult Guide Sheath**Jul 29, 2022  
29 days to decisionK221914 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k221914/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jun 30, 2022
Decision date	Jul 29, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Contract Medical International S.R.O.</b>
Contact	Jan Kubicek

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221914/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026