

**K181463 DuraSheath Introducer Sheath System**Dec 13, 2018  
192 days to decisionK181463 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k181463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 4, 2018
Decision date	Dec 13, 2018
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contract Medical International, GmbH</b>
Location	Dresden, DE
Contact	Jan Kloboucnik
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/k181463/> 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