

**K100799 FORTRESS INTRODUCER SHEATH SYSTEM MODEL  
358813, 358814, 358815**Feb 25, 2011  
340 days to decisionK100799 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100799/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 22, 2010
Decision date	Feb 25, 2011
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contract Medical Intl. GmbH</b>
Location	Dresden, Sachsen, DE
Contact	JAN KLOBOUCNIK
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100799/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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