

K153197 Fortress Introducer Sheath SYstemJan 11, 2016
68 days to decisionK153197 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k153197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 4, 2015
Decision date	Jan 11, 2016
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Contract Medical International, GmbH
Location	Dresden, DE
Contact	JAN KLOBOUCNIK
510(k) history	7 submissions · 7 cleared · 2015-2025

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