

K142357 DuraSheath Introducer Sheath SystemJun 25, 2015
304 days to decisionK142357 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k142357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 25, 2014
Decision date	Jun 25, 2015
Days to decision	304 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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