

K124046 VALVED TEARAWAY INTRODUCER GENERATION IIJun 3, 2013
154 days to decisionK124046 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k124046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 31, 2012
Decision date	Jun 3, 2013
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Components, Inc.
Location	Mchenry, IL, US
Contact	TIMOTHY HOLWICK
510(k) history	63 submissions · 55 cleared · 1980-2025

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