

**K043438 LARGE BORE SPLITTABLE INTRODUCER KIT**Feb 15, 2005  
63 days to decisionK043438 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k043438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Dec 14, 2004
Decision date	Feb 15, 2005
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thomas Medical Products, Inc.</b>
Location	Malvern, PA, US
Contact	TIM STOUDT
510(k) history	23 submissions · 23 cleared · 1990-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043438/> 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 June 9, 2026