

K122431 HEARTSPAN STEERABLE INTRODUCER KITJan 29, 2013
172 days to decisionK122431 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k122431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 10, 2012
Decision date	Jan 29, 2013
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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