

**K120158 CORONARY SINUS GUIDE AND LATERAL VEIN
INTRODUCER KITS**Aug 14, 2012
209 days to decisionK120158 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k120158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 18, 2012
Decision date	Aug 14, 2012
Days to decision	209 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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