

**K112398 TRIV(TM) VALVED TEARAWAY INTRODUCER,
TIRV(TM) VALVED TEARAWAY INTRODUCER WITH SIDE PORT**Apr 12, 2012
237 days to decisionK112398 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k112398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 19, 2011
Decision date	Apr 12, 2012
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Galt Medical
Location	Buford, GA, US
Contact	BETSY CORTELLONI
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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