

K132498 VALVED TEARAWAY INTRODUCER GENERATION IINov 25, 2013
108 days to decisionK132498 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k132498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 9, 2013
Decision date	Nov 25, 2013
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medcomp (Medical Components, Inc.)
Location	Harleysville, PA, US
Contact	TIMOTHY HOLWICK
510(k) history	6 submissions · 6 cleared · 2013-2017

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