

K121404 SOLOPATH RE-COLLAPSIBLE ACCESS SYSTEMMay 3, 2013
358 days to decisionK121404 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k121404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 10, 2012
Decision date	May 3, 2013
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Onset Medical Corporation
Location	Mission Viejo, CA, US
Contact	JOSEPH BISHOP
510(k) history	8 submissions · 8 cleared · 2005-2016

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