

**K090867 AIRBLOC TRANSSEPTAL INTRODUCER, 53 CM,
MODEL FA001, AIRBLOCK TRANSSEPTAL INTRODUCER, 72
CM ,MODEL FA002**Jul 30, 2009
121 days to decisionK090867 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k090867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 31, 2009
Decision date	Jul 30, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ep Dynamics, Inc.
Location	Mission Viejo, CA, US
Contact	ALBERT REGO
510(k) history	2 submissions · 2 cleared · 2009-2012

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