

**K111603 LINEBACKER(TM) TRANSSEPTAL INTRODUCER,  
53CM / 62CM / 72CM**Aug 23, 2012  
442 days to decisionK111603 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111603/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 8, 2011
Decision date	Aug 23, 2012
Days to decision	442 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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