

**K110051 RADIALSOURCE TRANSRADIAL ACCESS  
INTRODUCER KIT**Feb 2, 2012  
391 days to decisionK110051 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110051/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 7, 2011
Decision date	Feb 2, 2012
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Great Batch Medical</b>
Location	Plymouth, MN, US
Contact	SARA BAKKER
510(k) history	10 submissions · 10 cleared · 2009-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110051/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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