

**K111644 MOBICATH TRANSSEPTAL NEEDLE**Oct 3, 2011  
112 days to decisionK111644 · Product code: **DRC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Jun 13, 2011
Decision date	Oct 3, 2011
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Great Batch Medical</b>
Location	Plymouth, MN, US
Contact	Kristi Fox
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/k111644/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026