

**K122832 MOBICATH TRANSSEPTAL NEEDLE**Dec 19, 2012  
93 days to decisionK122832 · Product code: **DRC** · CardiovascularSource: <https://www.510kdatabase.net/k122832/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Trocar (DRC)
Date received	Sep 17, 2012
Decision date	Dec 19, 2012
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Great Batch Medical</b>
Location	Plymouth, MN, US
Contact	DENISE THOMPSON
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/k122832/> 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