

**K080700 DUOFLO CATHETER**Sep 26, 2008  
199 days to decisionK080700 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k080700/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Mar 11, 2008
Decision date	Sep 26, 2008
Days to decision	199 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thermopeutix, Inc.</b>
Location	San Diego, CA, US
510(k) history	5 submissions · 5 cleared · 2008-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080700/>, 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 June 8, 2026