

**K083384 THERMODILUTION CATHETER**Jan 5, 2010  
414 days to decisionK083384 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k083384/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Nov 17, 2008
Decision date	Jan 5, 2010
Days to decision	414 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosensors Intl. Pte. , Ltd.</b>
Location	Singapore, SG
Contact	MOSES THAM
510(k) history	2 submissions · 2 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083384/> 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 21, 2026