

**K113335 HEARTRAIL III GUIDING CATHETER**Jul 16, 2012  
245 days to decisionK113335 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Nov 14, 2011
Decision date	Jul 16, 2012
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Corporation</b>
Location	Shibuya-Ku, Tokyo, JP
Contact	MARK UNTERREINER
510(k) history	13 submissions · 13 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113335/> 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 24, 2026