

**K092372 HEARTRAIL III GUIDING CATHETER**Sep 11, 2009  
37 days to decisionK092372 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k092372/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Aug 5, 2009
Decision date	Sep 11, 2009
Days to decision	37 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Corp.</b>
Location	Somerset, NJ, US
Contact	MARK UNTERREINER
510(k) history	21 submissions · 21 cleared · 1991-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092372/> 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