

**K113464 NC TREK OTW CORONARY DILATATION CATHETER**Mar 6, 2012  
105 days to decisionK113464 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Nov 22, 2011
Decision date	Mar 6, 2012
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Vascular</b>
Location	S,Mta Clara, CA, US
Contact	SUZANNE REDMAN
510(k) history	30 submissions · 30 cleared · 2009-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113464/> 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 14, 2026