

**K101361 REEFLEX PTA CATHETER**Aug 4, 2010  
82 days to decisionK101361 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k101361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 14, 2010
Decision date	Aug 4, 2010
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ClearStream Technologies , Ltd.</b>
Location	Austin, TX, US
Contact	FIONA N MHULLAIN
510(k) history	7 submissions · 7 cleared · 2008-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101361/> 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 18, 2026