

**K122379 FLASH PTA BALLOON DILATATION CATHETER - 4MM  
X 14MM X 135CM, FLASH PTA BALLOON DILATATION  
CATHETER - 4MM X 19MM X 135CM**Sep 5, 2012  
30 days to decisionK122379 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k122379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 6, 2012
Decision date	Sep 5, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ostial Corporation</b>
Location	Mountain View, CA, US
Contact	KAITLIN VON HOFFMANN
510(k) history	12 submissions · 11 cleared · 2011-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122379/>; 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 3, 2026