

**K120738 FLASH PTA BALLOON DILATATION
CATHETER-4.0X14MMX135CM**Mar 29, 2012
17 days to decisionK120738 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k120738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Mar 12, 2012
Decision date	Mar 29, 2012
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120738/> Data sourced from FDA 510(k) public records (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. - Generated June 3, 2026