

**K111284 FLASH-C PTCA BALLOON DILATION CATHETER -
5MM X 19MM X 135CM / 6MM X 19MM X 135CM**Aug 17, 2011
103 days to decisionK111284 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k111284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	May 6, 2011
Decision date	Aug 17, 2011
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111284/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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