

**K113775 FLASH-C PTCA BALLOON DILATATION CATHETER-
4.0MM X 14MM X 135CM -4.0MM X 19MM X 135CM- 4.5MM X
14MM X 135CM-4.5MM X 19MM**Jun 29, 2012
190 days to decisionK113775 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k113775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 22, 2011
Decision date	Jun 29, 2012
Days to decision	190 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

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