

**K122178 FLASH-C PTCA BALLOON DILATATION CATHETER -
4MM X 14MM X 135CM, FLASH-C PTCA BALLOON DILATATION
CATHETER - 4MM X 19MM X 1**

Oct 11, 2012
80 days to decision

K122178 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k122178/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jul 23, 2012
Decision date	Oct 11, 2012
Days to decision	80 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.net

Device record: <https://www.510kdatabase.net/k122178/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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