

K150946 FLASH Ostial System OTW-6.0mm x 12mm x 80cm, FLASH Ostial System OTW-6.0mm x 12mm x 135cm, FLASH Ostial System OTW-7.0mm x 12mm x 80cm, FLASH Ostial System OTW-7.0mm x 12mm x 135cmMay 8, 2015
30 days to decisionK150946 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k150946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 8, 2015
Decision date	May 8, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150946/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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