K133861 FLASH OSTIAL SYSTEM OTW-7.0MMX17MMX135CM, FLASH OSTIAL SYSTEM OTW-7.0MMX17MMX80CM

CLEARED

Jul 2, 2014
195 days to decision

K133861 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k133861/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Dec 19, 2013
Decision date	Jul 2, 2014
Days to decision	195 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