

K102035 SLEEK OTW PTA CATHETERSDec 1, 2010
135 days to decisionK102035 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k102035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 19, 2010
Decision date	Dec 1, 2010
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ClearStream Technologies , Ltd.
Location	Austin, TX, US
Contact	FIONA NI MHULLAIN
510(k) history	7 submissions · 7 cleared · 2008-2011

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