

K090364 EXTRA PTA BALLOON CATHETER WITH EMBOLIC PROTECTION FEATURE

Mar 23, 2010
403 days to decision

K090364 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k090364/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Feb 13, 2009
Decision date	Mar 23, 2010
Days to decision	403 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Angioslide, Ltd.
Location	Sandy Spring, MD, US
Contact	ELISA HARVEY
510(k) history	6 submissions · 6 cleared · 2010-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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