FDA 510(k) Premarket Notification

CLEARED

K141025 ARTIMES BALLOON DILATATION CATHETER

Sep 12, 2014
144 days to decision

K141025 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k141025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Apr 21, 2014
Decision date	Sep 12, 2014
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brosmed Medical**
Location	Dongguan, Guangdong, CN
Contact	STEPHEN LEE
510(k) history	2 submissions · 2 cleared · 2014-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141025/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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