

**K182699 Selethru PTCA Balloon Dilatation Catheter**Nov 26, 2018  
60 days to decisionK182699 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182699/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 27, 2018
Decision date	Nov 26, 2018
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kossel Medtech (Suzhou) Co., Ltd.</b>
Location	Suzhou, CN
Contact	Zane Wang
510(k) history	5 submissions · 5 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182699/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026