

**K211393 Selethru(TM) NC PTCA Balloon Dilatation Catheter**Jul 2, 2021  
58 days to decisionK211393 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k211393/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	May 5, 2021
Decision date	Jul 2, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kossel Medtech (Suzhou) Co., Ltd.</b>
Location	Suzhou, CN
Contact	Maggie Xu
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/k211393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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