

K211349 Selebrek PTCA Balloon Dilatation CatheterJan 7, 2022
249 days to decisionK211349 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k211349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	May 3, 2021
Decision date	Jan 7, 2022
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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