

K230705 POT PTCA Balloon Dilatation CatheterApr 11, 2023
28 days to decisionK230705 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k230705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Mar 14, 2023
Decision date	Apr 11, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brosmed Medical Co., Ltd.
Location	Dongguan, CN
Contact	Crystal Lee
510(k) history	8 submissions · 8 cleared · 2016-2025

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