

**K230374 Coronary Dilatation Balloon Catheter
(VesPenetrator®), Coronary Dilatation Balloon Catheter
(VesTraveler®), Coronary Dilatation Balloon Catheter
(VexPander®)**Jun 29, 2023
136 days to decisionK230374 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k230374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Feb 13, 2023
Decision date	Jun 29, 2023
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan TT Medical, Inc.
Location	Dongguan, CN
Contact	Yuying Bi
510(k) history	6 submissions · 6 cleared · 2023-2026

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