

K260437 Valvuloplasty Balloon Catheter (ValvuloPro)Mar 20, 2026
37 days to decisionK260437 · Product code: **OZT** · CardiovascularSource: <https://www.510kdatabase.net/k260437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Feb 11, 2026
Decision date	Mar 20, 2026
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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