

K240967 ValvuloPro Valvuloplasty Balloon CatheterJul 31, 2024
113 days to decisionK240967 · Product code: **OZT** · CardiovascularSource: <https://www.510kdatabase.net/k240967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Apr 9, 2024
Decision date	Jul 31, 2024
Days to decision	113 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240967/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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