

K231814 ValvuloPro Valvuloplasty Balloon CatheterOct 12, 2023
113 days to decisionK231814 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k231814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Jun 21, 2023
Decision date	Oct 12, 2023
Days to decision	113 days
Third-party review	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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