

K241562 OutFlo Aortic Valve Dilatation Balloon CatheterMar 11, 2025
284 days to decisionK241562 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k241562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	May 31, 2024
Decision date	Mar 11, 2025
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Disa Medinotec
Location	Johannesburg, ZA
Contact	Lyndon Oldfield
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Matthew Krueger

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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