

K253855 KardiaPSI Balloon CatheterMay 6, 2026
154 days to decisionK253855 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k253855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Dec 3, 2025
Decision date	May 6, 2026
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intervention Tech, Inc. ; dba Corvention
Location	Flagstaff, AZ, US
Contact	Ryan Smith
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Ikigai Medical Development
Contact	Natasha Bond

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026