

K240775 PeriBeam® Pericardial MembraneApr 18, 2025
393 days to decisionK240775 · Product code: **DXZ** · CardiovascularSource: <https://www.510kdatabase.net/k240775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Mar 21, 2024
Decision date	Apr 18, 2025
Days to decision	393 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tamabio
Location	Tokyo, JP
Contact	Tetsuya Nagao
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Nilo Medical Consulting Group, LLC
Contact	Michael Nilo

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240775/> 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 May 14, 2026