FDA 510(k) Premarket Notification

K240775 PeriBeam® Pericardial Membrane

CLEARED

Apr 18, 2025
393 days to decision

K240775 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k240775/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, 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