

K252126 MitraPatch Mitral Valve Repair SystemDec 4, 2025
150 days to decisionK252126 · Product code: **PAW** · Cardiovascular
Source: <https://www.510kdatabase.net/k252126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture For Chordae Tendinae Repair Or Replacement (PAW)
Date received	Jul 7, 2025
Decision date	Dec 4, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chawla Heart Technologies, LLC
Location	Bloomfield, CT, US
Contact	Surendra Chawla
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	CardioMed Device Consultants, LLC
Contact	Semih Oktay

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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