

K241035 PMT Posterior Cervical Stabilization System (PCSS)Jun 25, 2024
70 days to decisionK241035 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k241035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Apr 16, 2024
Decision date	Jun 25, 2024
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Providence Medical Technology, Inc.
Location	Lafayette, CA, US
Contact	Edward Liou
510(k) history	19 submissions · 19 cleared · 2012-2025

REGULATORY CONSULTANT

Consulting firm	R. Dubois Consulting
Contact	Roxanne Dubois

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

CLINICAL EVIDENCE - NCT04229017**Study of Posterior Cervical Stabilization System (PCSS) as Part of Circumferential Fusion to Treat Multilevel DDD**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	236 patients (estimated)
Study sites	17 sites
Condition studied	Degenerative Disc Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Dec 1, 2025
Sponsor	Providence Medical Technology, Inc. (Industry)

Primary outcome

Superiority in Fusion Success in CCF (treatment) compared to ACDF (control)

Secondary outcome

Non-inferiority Composite Safety Success in CCF (treatment) compared to ACDF (control)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04229017