

K253472 FIREFLY® Pedicle Screw Navigation GuideFeb 25, 2026
138 days to decisionK253472 · Product code: **PQC** · Orthopedic
Source: <https://www.510kdatabase.net/k253472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pedicle Screw Placement Guide (PQC)
Date received	Oct 10, 2025
Decision date	Feb 25, 2026
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mighty Oak Medical
Location	Englewood, CO, US
Contact	Mark Wylie
510(k) history	4 submissions · 4 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253472/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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