

K250602 X-PAC® N-GAGE™ Lumbar Plate SystemMay 20, 2025
81 days to decisionK250602 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k250602/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 28, 2025
Decision date	May 20, 2025
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Expanding Innovations, Inc.
Location	Mountain View, CA, US
Contact	Robert Jaramillo
510(k) history	8 submissions · 8 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Helix Medical, LLC
Contact	Carolyn Guthrie

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/k250602/> 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 13, 2026