

K250773 Luna® Ti Interbody Fusion SystemFeb 4, 2026
327 days to decisionK250773 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k250773/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 14, 2025
Decision date	Feb 4, 2026
Days to decision	327 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinal Elements, Inc.
Location	Carlsbad, CA, US
Contact	Cheryl Allen
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250773/> 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 14, 2026