

K251896 XeliteMed SuperM-Fix Spinal Bone CementJan 28, 2026
222 days to decisionK251896 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k251896/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 20, 2025
Decision date	Jan 28, 2026
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xelite Biomed , Ltd.
Location	New Taipei City, TW
Contact	Wei Chun Chang
510(k) history	3 submissions · 3 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251896/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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