

K243537 XeliteMed VertehighFix High Viscosity Spinal Bone Cement SystemApr 11, 2025
147 days to decisionK243537 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k243537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Nov 15, 2024
Decision date	Apr 11, 2025
Days to decision	147 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

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