

**K241775 XeliteMed VertehighFix High Viscosity Spinal Bone Cement**

Sep 18, 2024  
90 days to decision

K241775 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k241775/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 20, 2024
Decision date	Sep 18, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k241775/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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