

**K160879 CONFIDENCE™ High Viscosity Spinal Cement, VIPER®
and EXPEDIUM® Fenestrated Screw Systems**Dec 20, 2016
265 days to decisionK160879 · Product code: PML · Orthopedic
Source: <https://www.510kdatabase.net/k160879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Mar 30, 2016
Decision date	Dec 20, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International S?rl
Location	Lelocle, CH
Contact	KIRSTEN LEMULLER
510(k) history	4 submissions · 4 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160879/>; 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 26, 2026