

**K212489 BonOs Inject Bone Cement**Oct 28, 2021  
80 days to decisionK212489 · Product code: **PML** · Orthopedic  
Source: <https://www.510kdatabase.net/k212489/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Aug 9, 2021
Decision date	Oct 28, 2021
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NEO Pedicle Screw System

**APPLICANT**

---

Company	<b>Neo Medical SA</b>
Location	Villette (Lavaux), CH
Contact	Jonas Larsson
510(k) history	6 submissions · 6 cleared · 2017-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Meditec Consulting GmbH</b>
Contact	Sandra Soniec

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212489/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026