

**K254107 Refobacin Bone Cement R (110034355)**Apr 15, 2026  
117 days to decisionK254107 · Product code: **LOD** · Orthopedic  
Source: <https://www.510kdatabase.net/k254107/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Dec 19, 2025
Decision date	Apr 15, 2026
Days to decision	117 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biomet France</b>
Location	Valence, FR
Contact	Vanessa Gautier
510(k) history	1 submissions · 1 cleared · 2026-2026

---

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

Device record: <https://www.510kdatabase.net/k254107/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026