

**K192394 Hi-Fatigue Bone Cement**Dec 2, 2019  
90 days to decisionK192394 · Product code: **LOD** · Orthopedic  
Source: <https://www.510kdatabase.net/k192394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Sep 3, 2019
Decision date	Dec 2, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osartis GmbH</b>
Location	Dieburg, DE
Contact	Volker Stirnal
510(k) history	6 submissions · 6 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192394/> 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 26, 2026