

K032945 SIMPLEX XMay 25, 2004
246 days to decisionK032945 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k032945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Sep 22, 2003
Decision date	May 25, 2004
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corp.
Location	Mchenry, IL, US
Contact	DANNIELLE WHEELER
510(k) history	124 submissions · 121 cleared · 1976-2023

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...

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