

**K093864 AVS ALIGN PEEK SPACERS MODEL 48328XXX,
48326XXX**Mar 11, 2010
84 days to decisionK093864 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k093864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 17, 2009
Decision date	Mar 11, 2010
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corp.
Location	Mchenry, IL, US
Contact	KIMBERLY S LANE
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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