FDA 510(k) Premarket Notification

K083661 AVS TL PEEK SPACERS

CLEARED

Feb 27, 2009
79 days to decision

K083661 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k083661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 10, 2008
Decision date	Feb 27, 2009
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	KIMBERLY 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...