CLEARED

Jan 26, 2015
84 days to decision

K143163 AVS® AL and ALign PEEK Spacers, AVS® PL and UniLIF PEEK Spacers, AVS® TL PEEK Spacer, AVS® Navigator PEEK Spacer, AVS® ARIA PEEK Spacer, AccuLIF TL and PL Cage, AVS® Anchor-L Spacer, Aero-AL Lumbar Cage System

K143163 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k143163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Nov 3, 2014
Decision date	Jan 26, 2015
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	GARRY T HAYECK
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...