FDA 510(k) Premarket Notification

CLEARED

K151726 AVS AL and AVS ALign PEEK Spacers, AVS PL and AVS UniLIF PEEK Spacers, AVS TL PEEK Spacer, AVS Navigator PEEK Spacer, AVS ARIA PEEK Spacer

Jan 20, 2016
208 days to decision

K151726 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151726/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 26, 2015
Decision date	Jan 20, 2016
Days to decision	208 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...