FDA 510(k) Premarket Notification

CLEARED

K203531 XYPAN Expandable Lumbar Cage System

Jan 29, 2021
58 days to decision

K203531 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k203531/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 2, 2020
Decision date	Jan 29, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aegis Spine, Inc.**
Location	Englewood, CO, US
Contact	Woo Joong Kwon
510(k) history	5 submissions · 5 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith Lee May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov