FDA 510(k) Premarket Notification

CLEARED

K210044 Crystal Spinal System & Vertu Spinal System, Lucent Spinal System, Zeus Spinal System, Ceres-C Spinal System, Omega XP Spinal System

Jun 30, 2021
174 days to decision

K210044 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k210044/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 7, 2021
Decision date	Jun 30, 2021
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Elements, Inc.**
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026