FDA 510(k) Premarket Notification

CLEARED

Jul 7, 2021
135 days to decision

K210497 SeaSpine Spacer System NM (Hollywood, Hollywood VI, Pacifica, Redondo, Ventura), Vu a•POD-L NanoMetalene, SeaSpine Vu e•POD System, SeaSpine Vu a•POD Prime NanoMetalene Intervertebral, SeaSpine Shoreline ACS - Anterior Cervical Standalone, SeaSpine Cervical Interbody RT System, SeaSpine Cambria System, SeaSpine Regatta Lateral System, SeaSpine Reef TO/TA System, SeaSpine Reef TH System, SeaSpine Meridian System

K210497 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k210497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 22, 2021
Decision date	Jul 7, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**SeaSpine Orthopedics Corporation**
Location	Carlsbad, CA, US
Contact	Aly Alvarez
510(k) history	66 submissions · 66 cleared · 2016-2025