FDA 510(k) Premarket Notification

CLEARED

K201193 SeaSpine Spacer System NM (Hollywood, Hollywood VI, Pacifica, Redondo, Ventura), Vu a•POD-L NanoMetalene

Nov 25, 2020
205 days to decision

K201193 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 4, 2020
Decision date	Nov 25, 2020
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary
Other names	SeaSpine Vu e•POD System; and SeaSpine Reef TH System, SeaSpine Vu a•POD Prime NanoMetalene IBD; and SeaSpine Shoreline ACS, SeaSpine Cambria System; SeaSpine Regatta Lateral System; and SeaSpine Meridian System, Shoreline Cervical Interbody RT System; and SeaSpine Beachside System

APPLICANT

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