FDA 510(k) Premarket Notification

CLEARED

K201755 WaveForm L Interbody System, WaveForm TO Interbody System, WaveForm TA Interbody System

Dec 15, 2020
169 days to decision

K201755 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 29, 2020
Decision date	Dec 15, 2020
Days to decision	169 days
Third-party review	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