FDA 510(k) Premarket Notification

K192687 TrellOss™-L MPF

CLEARED

Jan 9, 2020
105 days to decision

K192687 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k192687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 26, 2019
Decision date	Jan 9, 2020
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nexxt Spine, LLC**
Location	Chesterland, OH, US
Contact	Andy Elsbury
510(k) history	22 submissions · 22 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting**
Contact	Karen E Warden

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