FDA 510(k) Premarket Notification

K201024 Expandable Titanium PLIF/TLIF System

CLEARED

Apr 29, 2021
374 days to decision

K201024 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201024/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 20, 2020
Decision date	Apr 29, 2021
Days to decision	374 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spectrum Spine, LLC**
Location	Colorado Springs, CO, US
Contact	James Robinson
510(k) history	4 submissions · 4 cleared · 2013-2021

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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