

K213493 Fortilink with TiPlus TechnologyJan 27, 2022
87 days to decisionK213493 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k213493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 1, 2021
Decision date	Jan 27, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Paradigm Spine
Location	New York, NY, US
Contact	Jessica Jho
510(k) history	3 submissions · 3 cleared · 2008-2022

REGULATORY CONSULTANT

Consulting firm	Surgalign Spine Technologies
Contact	Jessica Jho

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

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