

K211417 F3D-C2 Cervical Stand-Alone SystemFeb 4, 2022
273 days to decisionK211417 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k211417/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 7, 2021
Decision date	Feb 4, 2022
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Corelink, LLC
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

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](https://accessdata.fda.gov)

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