

K241846 E3D™-C Interbody SystemAug 12, 2024
47 days to decisionK241846 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k241846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 26, 2024
Decision date	Aug 12, 2024
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Evolution Spine
Location	Dallas, TX, US
Contact	Todd Wallenstein
Website	https://evolutionsspine.com
510(k) history	8 submissions · 8 cleared · 2021-2026

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