

K260038 E3D™-C Interbody SystemFeb 4, 2026
29 days to decisionK260038 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k260038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jan 6, 2026
Decision date	Feb 4, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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