

K242928 Tesera-k SC SystemApr 10, 2025
198 days to decisionK242928 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k242928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 24, 2024
Decision date	Apr 10, 2025
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kyocera Medical Technologies, Inc.
Location	Redlands, CA, US
Contact	Dennis Ty
510(k) history	15 submissions · 15 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
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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