

K212980 Tesera-k ALIF SystemJan 7, 2022
112 days to decisionK212980 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k212980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Sep 17, 2021
Decision date	Jan 7, 2022
Days to decision	112 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	Scott Rucker
510(k) history	15 submissions · 15 cleared · 2020-2025

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026