

K242771 Tesera-k PL System and Tesera-k XL SystemMar 20, 2025
188 days to decisionK242771 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k242771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 13, 2024
Decision date	Mar 20, 2025
Days to decision	188 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242771/> 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 14, 2026