FDA 510(k) Premarket Notification

K223105 Tesera-K SC System

CLEARED

Dec 22, 2022
83 days to decision

K223105 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k223105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 30, 2022
Decision date	Dec 22, 2022
Days to decision	83 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 Technologies**
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov