FDA 510(k) Premarket Notification

CLEARED

K261353 Tesera-K Anterior Lumbar Interbody Fusion (ALIF) System

Jul 15, 2026
82 days to decision

K261353 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k261353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Apr 24, 2026
Decision date	Jul 15, 2026
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary
Other names	Tesera-K XL System; Lumbar Anchor System

APPLICANT

Company	**Kyocera Medical Technologies, Inc.**
Location	Redlands, CA, US
Contact	Scott Rucker
510(k) history	16 submissions · 16 cleared · 2020-2026