FDA 510(k) Premarket Notification

K230808 PEEK SA Anterior Lumbar Interbody Fusion (ALIF) System

CLEARED

Apr 21, 2023
29 days to decision

K230808 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k230808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 23, 2023
Decision date	Apr 21, 2023
Days to decision	29 days
Third-party review	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