

**K230808 PEEK SA Anterior Lumbar Interbody Fusion (ALIF)
System**Apr 21, 2023
29 days to decisionK230808 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230808/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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