

K214047 EL CAPITAN Anterior Lumbar Interbody Fusion SystemMar 30, 2022
93 days to decisionK214047 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k214047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 27, 2021
Decision date	Mar 30, 2022
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Astura Medical
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	21 submissions · 21 cleared · 2016-2026

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