

K192492 EL CAPITAN Anterior Lumbar Interbody SystemApr 21, 2020
223 days to decisionK192492 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k192492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Sep 11, 2019
Decision date	Apr 21, 2020
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astura Medical, LLC
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	8 submissions · 8 cleared · 2018-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026