

K221399 ZIP™ MIS Interspinous Fusion SystemJul 8, 2022
56 days to decisionK221399 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k221399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	May 13, 2022
Decision date	Jul 8, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aurora Spine, Inc.
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	7 submissions · 7 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221399/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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