

K221049 Zavation VariSync Plate System and VariSync Spacer System

Aug 12, 2022
123 days to decision

K221049 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k221049/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Apr 11, 2022
Decision date	Aug 12, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zavation Medical Products, LLC
Location	Flowood, MS, US
Contact	Katie Motley
510(k) history	30 submissions · 30 cleared · 2018-2025

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Device record: <https://www.510kdatabase.net/k221049/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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