

K193000 Hexanium® ACIFOct 20, 2020
358 days to decisionK193000 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k193000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 28, 2019
Decision date	Oct 20, 2020
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinevision, S.A.S.
Location	Antony, FR
Contact	Anaelle Gallego
510(k) history	5 submissions · 5 cleared · 2018-2022

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