

K210359 Hexanium TLIFMar 10, 2021
30 days to decisionK210359 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k210359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 8, 2021
Decision date	Mar 10, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Lince Consulting, LLC
Contact	Sevrina Ciucci

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/k210359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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