

K223251 Hexanium PLIFDec 16, 2022
56 days to decisionK223251 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k223251/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 21, 2022 |
| Decision date | Dec 16, 2022 |
| Days to decision | 56 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

REGULATORY CONSULTANT

| | |
|-----------------|------------------------------|
| Consulting firm | Lince Consulting, LLC |
| Contact | Nancy Lince |

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

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