

K203802 X-Pac Expandable Lumbar Cage SystemJun 7, 2021
161 days to decisionK203802 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k203802/>**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 | Dec 28, 2020 |
| Decision date | Jun 7, 2021 |
| Days to decision | 161 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Expanding Innovations, Inc. |
| Location | Mountain View, CA, US |
| Contact | Robert Jaramillo |
| 510(k) history | 8 submissions · 8 cleared · 2020-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------------|
| Consulting firm | Kapstone Medical, LLC |
| Contact | Carolyn Guthrie |

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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