

K223065 Adcura® Sagittae® Lateral Lumbar Interbody Fusion DevicesOct 26, 2022
26 days to decisionK223065 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k223065/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Sep 30, 2022 |
| Decision date | Oct 26, 2022 |
| Days to decision | 26 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Adcura, Inc. |
| Location | Eden Prairie, MN, US |
| Contact | Andrew Rogers |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Empirical Technologies |
| Contact | Nathan Wright |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026