

**K192006 SIRION Lateral Lumbar Interbody System**Apr 2, 2020  
248 days to decisionK192006 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k192006/>**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         | Jul 29, 2019   |
| Decision date         | Apr 2, 2020  |
| Days to decision      | 248 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Astura Medical, LLC</b>            |
| Location       | Carlsbad, CA, US                      |
| Contact        | Parker Kelch                          |
| 510(k) history | 8 submissions · 8 cleared · 2018-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192006/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026