

**K212266 FIX-C PEEK Anterior Cervical Interbody System**Dec 21, 2021  
154 days to decisionK212266 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k212266/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Traditional  |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received         | Jul 20, 2021   |
| Decision date         | Dec 21, 2021   |
| Days to decision      | 154 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Jeil Medical Corporation</b>         |
| Location       | Deer Field, IL, US                      |
| Contact        | Dajung Lee                              |
| 510(k) history | 53 submissions · 53 cleared · 2002-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212266/> 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 14, 2026