

**K190380 nvc**Mar 21, 2019  
30 days to decisionK190380 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k190380/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Special  |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received         | Feb 19, 2019   |
| Decision date         | Mar 21, 2019   |
| Days to decision      | 30 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Nvision Biomedical Technologies, Inc.</b> |
| Location       | San Antonio, TX, US                          |
| Contact        | Diana Langham                                |
| 510(k) history | 24 submissions · 24 cleared · 2019-2026      |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------|
| Consulting firm | <b>Watershed Ideas Foundry</b> |
| Contact         | Jeffrey Brittan                |

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190380/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026