

**K203342 CONSTRUX Mini Ti Spacer System**Mar 18, 2021  
125 days to decisionK203342 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k203342/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 13, 2020
Decision date	Mar 18, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthofix, Inc.</b>
Location	Mckinney, TX, US
Contact	Natalia Volosen
510(k) history	57 submissions · 57 cleared · 1996-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203342/> 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