

**K150619 CONSTRUX Mini PEEK Spacer System, CONSTRUX
Mini PEEK Ti Spacer System**Sep 11, 2015
185 days to decisionK150619 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k150619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 10, 2015
Decision date	Sep 11, 2015
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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