

K142152 CONSTRUX MINI PEEKJan 8, 2015
155 days to decisionK142152 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k142152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 6, 2014
Decision date	Jan 8, 2015
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary
Other names	SPACER SYSTEM, TI SPACER SYSTEM, CERVICAL STAND ALONE SYSTEM

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/k142152/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026