

K211704 CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System, CONSTRUX Mini PTC Spacer System, CONSTRUX Mini Ti Spacer System, FORZA PEEK Spacer System, FORZA PTC Spacer System, FORZA Ti Spacer System, FORZA XP Expandable Spacer System, Lonestar Cervical Standalone System, PILLAR PEEK Spacer System, PILLAR SA PEEK Spacer System, PILLAR SA PTC Spacer System, SKYHAWK Lateral Interbody Fusion System

Aug 31, 2021
89 days to decision

K211704 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k211704/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 3, 2021
Decision date	Aug 31, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k211704/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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