

K211935 ORIO-Ti Intervertebral Body Fusion Cage SystemSep 30, 2021
100 days to decisionK211935 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k211935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 22, 2021
Decision date	Sep 30, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinecraft, LLC
Location	Westchester, IL, US
Contact	Ami Akallal-Asaad
510(k) history	12 submissions · 12 cleared · 2010-2023

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