

K233191 TotalTi ACDF by SAGICONov 21, 2023
54 days to decisionK233191 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k233191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 28, 2023
Decision date	Nov 21, 2023
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinal Analytics & Geometrical Implant Co, LLC
Location	Tampa, FL, US
Contact	James J. Gibson
510(k) history	2 submissions · 2 cleared · 2018-2023

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