

K203311 ChoiceSpine Blackhawk Ti Cervical Spacer SystemMay 10, 2021
181 days to decisionK203311 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k203311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Nov 10, 2020
Decision date	May 10, 2021
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Choice Spine, LLC
Location	Knoxville, TN, US
Contact	Kim Finch
510(k) history	9 submissions · 9 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203311/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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