

K222903 Tailored-H Cervical Stand Alone SystemNov 18, 2022
56 days to decisionK222903 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k222903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 23, 2022
Decision date	Nov 18, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bespoke Technologies, LLC
Location	Winston-Salem, NC, US
Contact	Daniel Hoehn
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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