

K200458 Tailored-C Cervical Interbody Fusion SystemDec 28, 2020
307 days to decisionK200458 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k200458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 25, 2020
Decision date	Dec 28, 2020
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bespoke Technologies
Location	Winston-Salem, NC, US
Contact	Daniel Hoehn
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 21, 2026