

K153122 Endoskeleton(r) TCS SystemDec 14, 2015
46 days to decisionK153122 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k153122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 29, 2015
Decision date	Dec 14, 2015
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Titan Spine, LLC
Location	Mequon, WI, US
Contact	Jane Rodd
510(k) history	14 submissions · 14 cleared · 2008-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153122/> 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 May 16, 2026