

K192570 Atlas Spine Expandable Cervical Standalone Interbody System

Feb 28, 2020
163 days to decisionK192570 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k192570/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 18, 2019
Decision date	Feb 28, 2020
Days to decision	163 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Atlas Spine, Inc.
Location	Jupiter, FL, US
Contact	Thomas Smith
510(k) history	15 submissions · 15 cleared · 2007-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192570/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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