

K192993 SCARLET AL-TJan 22, 2020
89 days to decisionK192993 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k192993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Oct 25, 2019
Decision date	Jan 22, 2020
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spineart
Location	Geneva, CH
Contact	Franck Pennesi
510(k) history	44 submissions · 44 cleared · 2008-2023

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