FDA 510(k) Premarket Notification

K181818 Scarlet AL-T

CLEARED

Oct 9, 2018
92 days to decision

K181818 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k181818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 9, 2018
Decision date	Oct 9, 2018
Days to decision	92 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