FDA 510(k) Premarket Notification

K181203 Juliet Ti

CLEARED

Jun 28, 2018
52 days to decision

K181203 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 7, 2018
Decision date	Jun 28, 2018
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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