FDA 510(k) Premarket Notification

K181397 DualX

CLEARED

Sep 27, 2018
121 days to decision

K181397 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 29, 2018
Decision date	Sep 27, 2018
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Innovasive, Inc.**
Location	Mission Viejo, CA, US
Contact	Andy Choi
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Empirical Consulting**
Contact	Meredith L. May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov