FDA 510(k) Premarket Notification

K152355 Twin Peaks Lumbar Interbody Fusion System

CLEARED

Dec 10, 2015
112 days to decision

K152355 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k152355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 20, 2015
Decision date	Dec 10, 2015
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineway**
Location	Ecully, FR
Contact	Julien Thao my
510(k) history	5 submissions · 5 cleared · 2015-2023