FDA 510(k) Premarket Notification

CLEARED

K153783 SpaceVision® PLIF, SpaceVision® OLIF, SpaceVision® TLIF

May 4, 2016
125 days to decision

K153783 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k153783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 31, 2015
Decision date	May 4, 2016
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinevision S.A.**
Location	Douglassville, PA, US
Contact	Helene PLAS
510(k) history	5 submissions · 5 cleared · 2012-2016