FDA 510(k) Premarket Notification

CLEARED

K173347 STALIF C FLX, STALIF M FLX, STALIF L FLX and STALIF Lateral-Oblique FLX, ACTILIF C FLX, ACTILIF M FLX, ACTILIF L FLX and ACTILIF Lateral-Oblique FLX

May 8, 2018
195 days to decision

K173347 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k173347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 25, 2017
Decision date	May 8, 2018
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Centinel Spine, Inc.**
Location	West Chester, PA, US
Contact	Jessica Staub
510(k) history	10 submissions · 10 cleared · 2012-2018