FDA 510(k) Premarket Notification

K170235 Lucent®

CLEARED

Nov 29, 2017
308 days to decision

K170235 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k170235/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 25, 2017
Decision date	Nov 29, 2017
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Elements, Inc.**
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026