FDA 510(k) Premarket Notification

K171495 Zyston Strut Open Titanium Spacer System

CLEARED

Feb 12, 2018
266 days to decision

K171495 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171495/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 22, 2017
Decision date	Feb 12, 2018
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Biomet Spine, Inc.**
Location	Broomfield, CO, US
Contact	Megan Fessenden
510(k) history	15 submissions · 15 cleared · 2017-2021