FDA 510(k) Premarket Notification

K191339 Zavation eZspand Interbody System

CLEARED

Aug 19, 2019
91 days to decision

K191339 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k191339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 20, 2019
Decision date	Aug 19, 2019
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zavation Medical Products, LLC**
Location	Flowood, MS, US
Contact	Matt Jones
510(k) history	30 submissions · 30 cleared · 2018-2025