FDA 510(k) Premarket Notification

K193255 Largo PEEK Interbody System

CLEARED

Feb 20, 2020
86 days to decision

K193255 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k193255/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 26, 2019
Decision date	Feb 20, 2020
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Flospine, LLC**
Location	Boca Raton, FL, US
Contact	Peter Harris
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov