FDA 510(k) Premarket Notification

K180071 STYLO Interbody Fusion Device

CLEARED

May 3, 2018
114 days to decision

K180071 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k180071/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 9, 2018
Decision date	May 3, 2018
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Legend Spine Technologies**
Location	Bethlehem, PA, US
Contact	Gwendolyn DeBoer
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Mrc/X, LLC**
Contact	Christine Scifert

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