FDA 510(k) Premarket Notification

K192208 CORNICE Cervical Spacer System

CLEARED

Oct 9, 2019
56 days to decision

K192208 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k192208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 14, 2019
Decision date	Oct 9, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Legend Spine Technologies**
Location	Bethlehem, PA, US
Contact	Steve Marinelli
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