FDA 510(k) Premarket Notification

K171046 SeaSpine Cambria System

CLEARED

Jul 7, 2017
91 days to decision

K171046 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k171046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Apr 7, 2017
Decision date	Jul 7, 2017
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**SeaSpine Orthopedics Corporation**
Location	Carlsbad, CA, US
Contact	Gina Flores
510(k) history	66 submissions · 66 cleared · 2016-2025