FDA 510(k) Premarket Notification

CLEARED

K183083 Shoreline Cervical Interbody RT System

Feb 14, 2019
100 days to decision

K183083 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k183083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 6, 2018
Decision date	Feb 14, 2019
Days to decision	100 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