FDA 510(k) Premarket Notification

CLEARED

K153352 Vertu® & Vertu® Ti-Bond and Crystal® & Crystal® Ti-Bond Cervical Interbody System

Aug 1, 2016
255 days to decision

K153352 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k153352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Nov 20, 2015
Decision date	Aug 1, 2016
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Elements, Inc.**
Location	Carlsbad, CA, US
Contact	Cecilia Silva
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026