FDA 510(k) Premarket Notification

K203520 Blustone Synergy Interbody Fusion System

CLEARED

Apr 7, 2021
127 days to decision

K203520 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k203520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 1, 2020
Decision date	Apr 7, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Blustone Synergy, LLC**
Location	Pueblo, CO, US
Contact	Tom Gentry
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

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