

K210382 Blustone Synergy Diamond SA Cervical SystemJul 23, 2021
164 days to decisionK210382 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k210382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Feb 9, 2021
Decision date	Jul 23, 2021
Days to decision	164 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](https://accessdata.fda.gov)

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