

**K171893 Blustone Synergy Lumbar Interbody Fusion System
(Basalt, Magma, Obsidian), Blustone Synergy Cervical
Interbody Fusion System (Slate)**

Sep 8, 2017
74 days to decision

K171893 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k171893/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Jun 26, 2017 |
| Decision date | Sep 8, 2017 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Blustone Synergy |
| Location | Pueblo, CO, US |
| Contact | Lisa Peterson |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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