

**K193359 SureMAX Family of Cervical Spacers**Jan 3, 2020  
30 days to decisionK193359 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k193359/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 4, 2019
Decision date	Jan 3, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Additive Implants, Inc.</b>
Location	Phoenix, AZ, US
Contact	Jeff Horn
510(k) history	2 submissions · 2 cleared · 2020-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193359/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026