

**K182114 FlareHawk Interbody Fusion System**Jan 7, 2019  
154 days to decisionK182114 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k182114/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 6, 2018
Decision date	Jan 7, 2019
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integrity Implants, Inc.</b>
Location	Jupiter, FL, US
Contact	Lauren Kamer
510(k) history	11 submissions · 11 cleared · 2019-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182114/> 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 26, 2026