

**K201367 FlareHawk TiHawk9 Interbody Fusion System**Sep 23, 2020  
124 days to decisionK201367 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k201367/>**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	May 22, 2020
Decision date	Sep 23, 2020
Days to decision	124 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/k201367/> 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