

**K243116 FlareHawk Interbody Fusion System**May 21, 2025  
233 days to decisionK243116 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k243116/>**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	Sep 30, 2024
Decision date	May 21, 2025
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integrity Implants Inc. Db a Accelus</b>
Location	Palm Beach Gardens, FL, US
Contact	Lauren Kamer
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243116/> 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 13, 2026