

K183184 FlareHawk Interbody Fusion SystemApr 3, 2019
135 days to decisionK183184 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k183184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 19, 2018
Decision date	Apr 3, 2019
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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