

K202198 FlareHawk Interbody Fusion SystemNov 3, 2020
90 days to decisionK202198 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k202198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 5, 2020
Decision date	Nov 3, 2020
Days to decision	90 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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