

K220453 FlareHawk Interbody Fusion System

Mar 24, 2022
35 days to decision

K220453 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k220453/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 17, 2022
Decision date	Mar 24, 2022
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220453/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026