

K212050 NGM WAVE PLIF CageDec 1, 2021
154 days to decisionK212050 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k212050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 30, 2021
Decision date	Dec 1, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	NGMedical GmbH
Location	Nonnweiler, DE
Contact	Stella Hahn
510(k) history	7 submissions · 7 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212050/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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