FDA 510(k) Premarket Notification

K261067 BEE PLIF Cage

CLEARED

Apr 30, 2026
29 days to decision

K261067 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k261067/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 1, 2026
Decision date	Apr 30, 2026
Days to decision	29 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	Jen McBride

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k261067/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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