FDA 510(k) Premarket Notification

K231371 BEE Cervical Cage

CLEARED

Jan 12, 2024
245 days to decision

K231371 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k231371/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	May 12, 2023
Decision date	Jan 12, 2024
Days to decision	245 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