FDA 510(k) Premarket Notification

K203444 BEE HA Cage

CLEARED

Mar 18, 2021
115 days to decision

K203444 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k203444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 23, 2020
Decision date	Mar 18, 2021
Days to decision	115 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