FDA 510(k) Premarket Notification

K222256 BonOs® Inject Bone Cement

CLEARED

Aug 26, 2022
30 days to decision

K222256 · Product code: **PML** · Orthopedic
Source: https://www.510kdatabase.net/k222256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Jul 27, 2022
Decision date	Aug 26, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NEO Pedicle Screw System™

APPLICANT

Company	**Neo Medical SA**
Location	Villette (Lavaux), CH
Contact	Jonas Larsson
510(k) history	6 submissions · 6 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Meditec Consulting GmbH**
Contact	Sandra Soniec

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