FDA 510(k) Premarket Notification

K222789 VADER® Pedicle System, G21 Cement

CLEARED

Jan 9, 2023
116 days to decision

K222789 · Product code: **PML** · Orthopedic
Source: https://www.510kdatabase.net/k222789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Sep 15, 2022
Decision date	Jan 9, 2023
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Icotec AG**
Location	Altstaetten, SE
Contact	Marina Hess
510(k) history	16 submissions · 16 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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