FDA 510(k) Premarket Notification

K230774 PERLA® TL System

CLEARED

Jun 23, 2023
94 days to decision

K230774 · Product code: **PML** · Orthopedic
Source: https://www.510kdatabase.net/k230774/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Mar 21, 2023
Decision date	Jun 23, 2023
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TEKTONA® HV US Bone Cement

APPLICANT

Company	**Spineart**
Location	Geneva, CH
Contact	Franck Pennesi
510(k) history	44 submissions · 44 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Michael Coladonato

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