FDA 510(k) Premarket Notification

K220131 KYPHON VuE Bone Cement

CLEARED

Apr 18, 2022
90 days to decision

K220131 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k220131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jan 18, 2022
Decision date	Apr 18, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tecres S.P.A.**
Location	Bethesda, MD, US
Contact	Massio Grazioli
510(k) history	14 submissions · 14 cleared · 2005-2025

REGULATORY CONSULTANT

Consulting firm	**Brauer Device Consultants, LLC**
Contact	Christine Brauer

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