

K220131 KYPHON VuE Bone CementApr 18, 2022
90 days to decisionK220131 · 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](https://accessdata.fda.gov)

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