

K220640 Bifix Hybrid Abutment CementAug 23, 2022
172 days to decisionK220640 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k220640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Mar 4, 2022
Decision date	Aug 23, 2022
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Voco GmbH
Location	Denver, CO, US
Contact	M. Th. Plaumann
510(k) history	119 submissions · 119 cleared · 1991-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220640/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026